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A FRAMEWORK FOR THE CONTROL OF TOXIC SUBSTANCES (A COMPILATION OF SPEECHES)

Glenn E. Schweitzer

Environmental Protection Agency
Washington, D. C.

April 1975

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A FRAMEWORK FOR THE CONTROL OF TOXIC SUBSTANCES

A Compilation of Speeches by

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Washington, DC 20460

April 1975

PREFACE

This collection of speeches by the Director of the Office of Toxic Substances in large measure reflects the evolution of the interests, policies, and programs of the Office from April 1973 to March 1975. In most cases, the activities of the Office have reflected broad national concerns of interest to many Federal agencies and to many non-Governmental organizations. Hopefully, this collection, and particularly the more recent statements, will be helpful to specialists and other persons concerned with Governmental policies and objectives in this field.

Many of the ideas set forth in the speeches originated with different members of the Office staff, and these contributions are gratefully acknowledged. Also deserving special recognition is the unfailing secretarial assistance of Mrs. Willie Wheeler and Ms. Carol Kilgore in preparing texts that are invariably put into final form under very tight deadlines just prior to the presentations.

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TOXIC SUBSTANCES: LEGISLATION, GOALS, AND CASE STUDIES

The Fourth Annual Conference on
Environmental Toxicology
University of California, Irvine
Fairborn, Ohio
October 16, 1973

I had hoped to be able to report to you today on the passage of the Toxic Substances Control Act of 1973 and the initial steps being undertaken in the implementation of this new law. However, there are a number of complicated aspects of the legislation, and it will still be some time until the conferees for the Senate and the House are able to reconcile the differences that exist in the two versions of the bill passed in July by these bodies. We are optimistic that agreement soon will be achieved on all provisions and that this much needed regulatory authority to control toxic substances will become law.

In view of the uncertainty as to the details of the proposed legislation, I have decided to refer to its specific provisions only briefly today and then concentrate on some of the broader aspects of our overall program. Specifically, I plan to set forth some of the general goals of our approach to the control of toxic substances and then discuss several case histories of very recent concern to us, the problems toxic substances are causing in these instances, and those aspects of the problems of particular interest in toxicologists.

TOXIC SUBSTANCES CONTROL ACT

The proposed Toxic Substances Control Act would give EPA new authority for (a) information acquisition, and (b) restrictive actions. EPA could require testing of chemical substances (both existing and new) which are suspected to pose unreasonable risks and also require other information from manufacturers including the name of the substance, chemical formula, amounts produced, actual or intended uses, and known by-products. EPA could then restrict the use and distribution of chemical substances found to pose unreasonable risks. The Agency could prescribe the amounts of a chemical which may be sold to processors, limit the type of processor to whom it may be sold, restrict the amount a given type of processor may use, or limit the sale or manner in which a substance may be used, handled, labelled, or disposed by any person.

This new authority is important from two standpoints. First, the Federal Government is given direct authority to restrict substances presently in commercial use that are known to cause health or environmental hazards, and when effects information is lacking, to require testing of the substance by the manufacturer to assess human or environmental impact. Second, for substances not yet in commercial production, the Agency could require premarket testing and review of chemicals suspected to be hazardous. The Agency would have the opportunity to assess the risks before the new substances are commercially produced and to take appropriate regulatory action to prevent toxic incidents.

Given the extensive scope of the legislation, the number of areas of initial emphasis will depend to a significant degree on the staff and resources available for implementation activities. In selecting areas for priority attention consideration should be given to Congressional mandates, severity and urgency of existing problems which can be alleviated by the new authority, opportunities to reduce future problems of major dimensions, and necessity for establishing long-term viability of implementation procedures.

While the final version of the legislation may influence the choice of initial activities, it seems clear that the following activities should be high on the agenda for early attention:

— Elaboration and articulation of the criteria or sets of criteria to be used in weighing risks versus benefits, and in determining when regulatory action is needed. Clear understanding by both industry and Government of the ground rules for restrictions is essential to the viability of industrial R & D activities.

— Determination of the character and scope of initial testing requirements, including the possibility of umbrella testing requirements for a broad range of chemical classes, and identification of specific chemicals or classes or chemicals of particular immediate concern. While the selection of substances covered by the standards for test protocols that are initially promulgated will in large measure reflect intuitive judgments concerning likely hazards and inadequacy of current data, concurrent work is needed to provide a basis

over the longer term for selecting areas of concern.

— Development of regulations setting forth timing, coverage, content, and format of the reporting requirements for chemical manufacturers and processors, including both annual reporting and premarket notification, as appropriate.

— Establishment of a data system for handling the industrial reports and test results that are submitted. Experience in the pesticide area underscores the importance of early attention to establishing efficient and decision oriented procedures to be effective when the first reports arrive.

PROGRAM GOALS

Considering our program in its broadest sense, our goals are quite straight forward and are directed to:

— clarification of the risks to health and the environment associated with the manufacture, distribution, use, and disposal of new and existing chemical substances, with particular regard to chemical properties, production levels and trends, and exposure of the chemicals to man and the environment;

— more effective utilization of regulatory authorities and related tools available to the Agency to mitigate such risks, taking into account the economic and social impact of restrictions on toxic substances; and

— increasing the concern of and appropriate actions by the chemical and related industries to reduce risks to health and the environment associated with their activities.

Of particular interest is the emphasis placed on the responsibility of industry, for it is the course taken by industry—with and without direct Governmental encouragement—which will largely determine the environmental risks posed by chemical substances in the years ahead. The importance of this industrial stewardship is apparent when it is realized that the annual value of chemical substances manufactured in the United States which are not subject to existing regulatory authorities exceeds $150 billion.

Now let us turn to several specific activities of interest, starting with the concept of *early warning*. In this area our general goal is to identify and prioritize previously unsuspected chemicals entering the environment which are most likely to pose a significant hazard to man or the environment in the near future. Subgoals include:

— Criteria: To develop criteria and techniques for determining on the basis of minimal information which chemical substances should be of greatest concern.

— Expert Opinion: To mobilize and use expert opinion to assist in rapidly screening large numbers of chemicals and predicting potential problem substances.

— Data Analysis: To collect, collate, and synthesize data from sources such as monitoring, trend assessment, and industrial reporting on those chemicals which appear to deserve the highest priority in a manner that will facilitate judgments as to whether the chemicals should be candidates for further investigations, testing, and/or control.

A second activity which is of particular interest to this group is *testing*. In general, we are attempting to improve the approaches by Government, industry, and the scientific community to testing of chemical substances entering commerce. Again, I would like to underscore the role of our industrial firms as we delineate our subgoals:

— Industrial Stewardship: To encourage increased industrial concern and appropriate action in testing both new and existing chemicals.

— Regulatory: To require or encourage, as appropriate, industrial testing of specific chemicals for which inadequate data concerning the risks associated with the chemicals is available but which are suspected to pose a hazard to man or the environment.

— Experimental: To provide experimental data needed to determine appropriate standards or restrictions for specific chemicals of near-term concern.

— Public Awareness: To bring test data concerning the safety of chemicals into public view, in a way that will not compromise trade secrets, thus facilitating a broader base of understanding and inputs for evaluating the necessity for restrictions for such chemicals.

A third area of interest is *research*, recognizing the overlaps between activities that are classified as research and programmatic activities. While the research interests of EPA encompass many areas, the three types of activities of priority interest to my Office are:

— Test Methods: To stimulate development of faster, cheaper, and/or more reliable test methods, with particular emphasis on approaches that provide data needed for specific types of regulatory actions.

— Trend Assessment: To improve assessments and forecasts of technological developments, economic and market trends, and material production and use patterns which can assist in anticipating environmental problems resulting from chemical substances entering the environment.

— Estimation of Exposure: To develop and apply methods and background data needed for assessing the extent of environmental and human exposure to selected chemical substances, including consideration of environmental transport, persistence, routes of entry into the environment, bioconcentration and bioaccumulation, environmental degradation, and retrospective, and retrospective monitoring through sample banking.

CASE HISTORIES

Recent discovery of hexachlorobenzene (HCB) in the fat of animals brought to slaughter has focused attention on the hazards of this material. The most serious case involved cattle in central Louisiana. Other incidents of HCB contamination in the past year have involved sheep in western Texas and in eastern California. Sources of HCB in Louisiana appear to be airborne emissions of manufacturing plants which produce chlorinated hydrocarbons and waste disposal practices of these plants. The Texas and California situations have been associated with pesticides which were contaminated with HCB.

An immediate problem confronting EPA earlier this year was the determination of a permissible level of residues of HCB in food. In response to a request from the Department of Agriculture, EPA reviewed available data on the toxicology of HCB, and concluded that it was not adequate to permit establishment of a tolerance level for HCB in food. This was confirmed in consultations with scientists in the Departments of Agriculture and Health, Education, and Welfare, and with other members of the scientific community.

Nevertheless, HCB occurs in food frequently enough that some guidance is necessary to protect public health. An experience in Turkey in the mid-fifties vividly demonstrated the health effects of HCB when ingested over a long period. There is, however, no experience which indicates the effects of low doses on humans. Attempts in the United States and abroad to determine the safe level of HCB in experimental animals have been extremely limited and sporadic, and at present there is a lack of authoritative data. Experiments on a variety of animals have been limited in design, scope, and duration. Meaningful inferences are difficult to draw although there are indications that repeated dosages of HCB at low levels may be harmful.

Related to these uncertainties is the unknown extent which meat products with low levels of HCB residues are likely to reach individual consumers on a repetitive basis. The sources of HCB of immediate concern are confined to very small geographic pockets which traditionally disperse a significant portion of their products to markets around the country. Similarly, little information is available for assessing the economic impact of alternative tolerance levels. In the original Louisiana quarantine area, for example, there were up to 20,000 food animals with HCB in their fat at levels ranging from 0.1 to 6.0 ppm. However, the extent that these levels could be reduced through fattening with clean feed and through natural processes prior to slaughter is uncertain. Similarly, the cost and success of biochemical methods to reduce the levels are difficult to assess. There are many other economic costs related to establishing a tolerance including the impact on the value of contaminated land, the costs of alternative feed supplies and the long-term impact on animal herds. Data are not available to assess these types of impact. Furthermore, the extent and levels of HCB residues which will appear in the months and years ahead in many areas of the country cannot be predicted.

On June 1, EPA recommended an interim action guideline of 0.5 ppm HCB in the fat of cattle, swine, sheep, horses, and goats at the time of slaughter. This was based on analysis of the best data available, including toxicological studies and economic considerations. At the same time several toxicological, epidemiological, ecological, and economic studies are being launched to provide an improved basis for determining the permissible level as the guideline is periodically reviewed.

A second set of interesting case histories relates to the emission standards for hazardous pollutants established in April of this year under the Clean Air Act. Limitations were set on mercury, asbestos, and beryllium. While toxicologists have been concerned with these standards, toxicology data which is useable in quantifying an acceptable level of risk for these substances has been conspicuous by its absence.

In the case of asbestos, the association between occupational exposure to asbestos and higher-than-expected incidence of bronchial cancer was recognized. Also, asbestos has been identified as a causal factor in development of cancers of the membrane lining the chest and abdomen. However, the lack of adequate quantitative data correlating asbestos exposure to these and other malfunctions, together with the difficulty in measuring asbestos emissions, made establishment of allowable numerical concentrations impractical. Therefore, the standard relies largely on limitations on visible emissions and on the specification of related air cleaning technologies.

With regard to beryllium, the AEC limit of 0.01 micrograms/cubic meter, which was set in 1949, has been adopted as the basis for the emission standard. In the period since the implementation of the AEC guideline, no reported cases of chronic beryllium disease have occurred as a result of community exposure, and the Committee on Toxicology of the National Academy of Sciences has concluded that the AEC guideline represents a safe level of exposure.

Now turning to mercury, it seems clear that the airborne burden must be considered together with the water- and food-borne burdens. An expert group concluded, based on its analysis of several episodes of mercury poisoning in Japan, that 4 micrograms of methylmercury per kilogram of bodyweight per day would result in the intoxication of a sensitive adult; application of a safety factor of 10 yielded an acceptable exposure of about 30 micrograms per day for a 70-kilogram man, and this level is also believed to provide satisfactory protection against genetic lesions and poisoning of the fetus and of children. It has been estimated that from average diets, over a considerable period, mercury intakes of 10 micrograms per day may be expected, so that, in order to restrict total intake of 30 micrograms per day, the average mercury intake from air would have to be limited to 20 micrograms per day. Assuming inhalation of 20 cubic meters of air per day, the air could contain an average daily concentration of no more than 1 microgram of mercury per cubic meter. Thus, this level serves as the basis for the standard.

A third type of case history concerns current efforts to set toxic pollutant effluent standards under the Federal Water Pollution Control Act. On September 7, EPA gave notice that standards would be set on nine toxic pollutants. This standard setting activity is currently underway with a publication date of early December for the proposed standards. Included on the list of pollutants are cyanide whose acute toxicity properties are of major concern, cadmium and mercury which are associated with major chronic toxicity problems, and benzidine, a known carcinogen. The adequacy of toxicological data for supporting these standards varies from substance to substance, but I can assure you that in some instances it is sorely lacking. Nevertheless, in all nine cases we are faced with the necessity to make judgments as to an acceptable level or risk. When the proposed standards are promulgated, the toxicology community hopefully will take the time to offer suggestions for improving the proposed approaches, for refining the interpretations of test data, and for generally pointing the way for future standard setting activities as they relate to the use of toxicological data.

In short, there are two types of problems related to toxicological data in setting standards in the near-term. First, how can the minimal test data which is available be most effectively used; and, secondly, how can future testing activity be best oriented to provide useable data for refining at a later date the standards that are being set? As an outsider with only brief exposure to the standard setting process and to the use of toxicological data, I have the general impression that there is not a good impedance match, at least in some areas, between standard setting needs and the orientation of testing activities. Furthermore, it appears that this difficulty is largely attributable to the failure of those of us responsible for programs to articulate our needs sufficiently far in advance to enable the scientific community to respond.

As we prepare to set standards for test protocols and to consider restrictive actions under the Toxic Substances Control Act, the importance of clear articulation of program needs takes on even greater significance. I am confident that in the years ahead, we will erode the communication difficulties between the program operators and the research community with society being the beneficiary.

Scientific data is interesting, but only if it is useable. Or in the words of Frank Lloyd Wright, "Science can only give us the tools in a box. . . .but of what use to us are miraculous tools until we have mastered the human, cultural use of them?"

ECONOMIC ASPECTS OF TOXIC SUBSTANCE CONTROL

Symposium on Economics of a Clean Environment
The Mitre Corporation
McLean, VA.
January 16, 1974

MILESTONES DURING 1973

Several toxic substance milestones during 1973 vividly illustrated the complexities of risk and benefit assessments.

- The chemical industry is still reverberating from the Department of Labor's stringent interim standards for handling 14 carcinogens, including several of considerable commercial importance.
- FDA banned the use of DES as a feed additive over the strong objections of the cattle ranchers.
- EPA's promulgation of final air emission standards and proposed water effluent standards for toxic pollutants are causing major adjustments in manufacturing practices at many facilities.
- Promulgation of final leaded gasoline regulations culminated several years of effort to address the severity of the problem of lead inhalation and human health.
- Discovery of high levels of asbestos fibers in the Duluth water supply has catalyzed a large array of technical talent to address what could turn out to be either a sleeping giant or a false alarm of major dimensions.
- The tussock moth outbreak on the West Coast highlighted the environmental and economic "disbenefits" resulting from the ban on DDT.
- The contamination of cattle in Louisiana and sheep in California with hexachlorobenzene—a by-product of chemical plants and also a contaminant in pesticides—clearly showed that the balancing of very uncertain toxicological, epidemiological, and economic data is often a near-term necessity.

WHAT IS UNIQUE IN ADDRESSING TOXIC SUBSTANCES?

There are essentially two aspects of the toxic substance problem, namely:

- Steps to clarify and mitigate, as appropriate, the risks associated with chemicals which are believed to pose a problem; and
- Selection from the remaining universe of commercial chemicals—numbering more than 20,000—those chemicals which deserve attention to determine if they pose an actual or potential problem.

With regard to the first aspect—namely, reducing the risks from suspected chemicals—the approach to risk/benefit analysis is probably not much different than assessment of the risks and benefits associated with other products and pollutants. Determination of the risk/benefit relationship is based largely on value judgments, and not quantifiable approaches. As with almost all environmental control measures, assessment of the environmental gain to society from proposed control measures is usually difficult. Assessment of the economic and social impact of specific limitations must take into account secondary and delayed effects, as well as the more obvious immediate effects.

Toxicological and epidemiological data are usually the starting point for a numerical standard. These data are frequently spotty, more often than not generated for scientific rather than regulatory purposes, and plagued with interpretation difficulties. Frequently, for toxic substances, the law constrains the balancing of this data on risks with available data on benefits in arriving at an appropriate standard (e.g., certain sections of the Clean Air Act and the Federal Water Pollution Control Act). However, this disregard of benefits is not the recommended approach. There should be a balancing of risks and benefits, and indeed in most regulatory actions there has been some balancing which is often subsumed in adjusting safety factors and other parameters affecting the standard. Even if the substance of concern has a clear "no-effects" threshold, this threshold is not necessarily the appropriate level for setting the standard. For all substances—including toxic substances which cause similar effects—the risk component derived from scientific data should be appropriately adjusted to take into account exposure levels and to balance the risks with the benefits.

While the approach to suspected chemicals seems reasonably straightforward, the risk/benefit aspects in the search for the other bad actors in the universe of chemicals cannot be easily described. How much is society ready to pay to search out these problem substances before they emerge on the immediate horizon? This question is the heart of the

"uniqueness" of the economics of toxic substances.

Another difference between toxic substances and gross pollution concerns relates to the environmental impact of control measures. While it is relatively easy to begin to quantify the economic value of clean rather than dirty water, the effects of toxic chemicals cannot be aggregated and the chemicals must be considered one by one.

Toxic substance activities are particularly sensitive to our lack of analytical and monitoring capability to detect the trace amounts of some chemicals that should be of concern. A sensitive capability is particularly important in dealing with very small amounts since very slight deviations can represent very large proportional changes. Frequently, the concentration of interest is below the level of detection; in some cases in the past we have been sufficiently clever to devise ways to monitor indirectly and to enforce limitations below this level. In addition standard reference materials have too long been neglected as is currently being demonstrated in our efforts to acquire comparable data at different laboratories on asbestos.

SOME CONSIDERATIONS IN RISK/BENEFIT ANALYSIS

Toxic substance problems arise in several forms:

* Effluents, emissions, solid wastes, and other by-products of manufacturing activities.
* Spills and other accidental releases.
* Worker or consumer exposure in a closed environment to a toxic substance associated with a product.
* Other direct exposure of man and/or the environment to a troublesome product, either in its intended or unintended use.
* General build-up of the chemical in the environment from natural, multiple, or unknown sources.
* Potential exposure of a product that has not yet reached the market place.

A variety of control strategies, in addition to simply installing well-known pollution control technologies, are obviously available in addressing these classes of problems. Such strategies include banning the product, restricting the use of the product, or requiring certain types of labels. Also of increasing interest are financial incentives attached to product lines (e.g., disposal charge, product tax) which will encourage recycling and/or appropriate disposal techniques.

Limitations on new products require particular care. At first appearance, it would seem easier for society to rationalize limitations on a product which does not have behind it a significant manufacturing investment than restrictions on a product already in commerce. However, this approach grossly oversimplifies sensible benefit analyses. Also, in determining future benefits to society of substances, the economic potential of the market should not be the only indicator. Rather, there should be an assessment of the total social benefit of the product, recognizing that this is easier said than done. Finally, in some cases there may be near-term economic disadvantages in spending R&D resources for duplicative products; but given the shifting nature of our industrial fabric and consumer patterns, in the long run there may be economic advantages in such an approach.

Related to the limitations on new products are the effects of limitations on incentives for industrial R&D, including both the direct effects on specific products and the cumulative and indirect effects on the R&D climate. In recent months, for example, several large firms have abandoned R&D on pesticides in view of regulatory disincentives for this type of activity.

Finally, in the long run, public confidence in the national approach to the control of toxic substances will be a decisive factor. Thus, individual decisions should take into account public concerns, and should be cast in terms understandable and persuasive to the layman.

INTERNALIZATION OF SOCIAL COSTS

Recent interest in the "internalization" of social costs of environmental pollution has focused in large measure on effluent fees or taxes. Where the industrial discharge is an unwanted (but at least, for the moment, unavoidable) by-product from the production of desired goods or services, and where the benefits and social costs inherent in the externalized subsidy of this production are not equitably shared, such an effluent tax provides a potential mechanism for amelioration of the inequalities.

The control of adverse effects from toxic chemicals involves somewhat different concepts, and internalization of social costs presents inherently more complex problems. Three sources of adverse effects may be cited:

— The unavoidable side effects from the intended use of the product (e.g. environmental contamination with lead from the use of TEC in motor fuels).

— The use of a product in ways not intended by the manufacturer (e.g. use of PCB's as heat exchange fluids in food processing plants).

— The disposal of the product after completion of the intended use (e.g. mercury contamination from disposal of batteries or flourescent tubes).

Approaches to internalize social costs by fees or taxes should satisfy three criteria. They should be

— effective in motivating changes in behavior that tend to reduce the social costs.

— equitable in allocating benefits and burdens upon the various affected segments of society.

— efficient in transferring the dollar costs imposed upon the user of the "toxic material" to those responsible for ameliorating damage or the loss in environmental quality.

The costs to society associated with toxic substances include:

— Costs of the regulatory agencies.

— Economic losses from condemnations or destruction of products already in commerce.

— Added costs of products as a result of higher development costs and lessened productivity of industrial R&D.

— Loss of benefits from products not reaching the marketplace.

Benefits accruing to society include both abatement of environmental hazards from existing chemicals and avoidance of environmental hazards by anticipatory actions. In all probability, even in the immediate future, the hidden costs and benefits will far outweigh the direct measurable costs and benefits, thus further complicating any type of comprehensive approach to internalizing costs.

THE ENERGY CRISIS AND TOXIC SUBSTANCES

There are a variety of concerns related to toxic substances as the energy crisis begins to impact on the economy. Cutbacks in petroleum feed stocks could drive industry to new processes and product mixes involving toxic substances. However, at this time there is no reason to expect a relaxation of safety standards by industry or Government to ease the accommodation of such new processes and products.

A more troublesome problem relates to the by-products of new energy sources, e.g., vanadium associated with oil shale, toxic metals found in coal, acid run-off from strip mines. Specific regulatory steps may be necessary in these cases to insure that environmental concerns are not lost in the race for new energy sources.

A final consideration concerns environmental control strategies which could lead to greater energy requirements. Environmental restrictions that reduce manufacturing efficiency are in this category. Also, specific product restrictions could aggravate energy problems. For example, the DES ban has forced the use of less efficient feed additives. As a second example, a limitation on the use of mercury in flourescent lights would force a return to incandescent bulbs which require two and one-half times as much energy per unit of light.

TOXIC SUBSTANCES IN THE MID-1980'S

By 1985, more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently suspected effects.

From the toxic substance point of view the quality of life in the chemical age of the Eighties, relative to the current quality of life, depends, in large measure, on the outcome of the competition between population and economic growth on the one hand and the sophistication in approaches to responsible regulation—by both industry and government. Clearly, more people will be exposed to more chemicals in more situations. Hopefully, we can develop the necessary precuationary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly toward toxic substances through its Governmental and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts. To avoid such a

situation, the highest quality of government leadership in this area is essential—leadership characterized by technical credibility and openness in dealing with controversial data.

If the regulatory pattern of the Sixties and Seventies continues, during the Eighties the number of toxic substances other than chemicals associated with foods, drugs, cosmetics, and pesticides regulated by Government will be relatively few—in the dozens rather than hundreds or thousands. However, each of these regulatory decisions will be significant in that they will set the framework and the standards for the efforts of industry in self-regulation of the bulk of the industrial chemicals.

Industry will probably be using testing and related approaches to product safety which are not significantly different from current approaches. The Governmental thicket of regulations will undoubtedly drive some of the smaller companies out of new product development. Concurrently, closer Governmental scrutiny of industry activities will be necessary in the face of potential antitrust problems as the larger companies consolidate their positions.

By 1985, most of the emission stacks and effluent pipes will be plugged. Our toxic substance concerns will center largely on contaminants, non-point sources, direct product exposure, and generally unattributable build-up of toxic chemicals in the environment. And, as the gross pollution effects subside, previously undetected effects of individual and combinations of chemicals in the water and in the air will probably be unmasked.

Risk/benefit approaches should be well accepted within a decade, although concerns will penetrate much more deeply into social as well as economic values. There should be far less concern over public acceptance of the concept of accepting different levels of risk for different chemicals, depending on their social utility. Indeed, the economics of a clean environment should be much closer to a reality.

Note: This text is based on contributions by a number of panel members.

1974—A YEAR OF TRANSITION

Seminar on Early Warning Systems for
Toxic Substances
Battelle Memorial Institute
Seattle, Washington
January 31, 1974

During the past several weeks, talk in Washington has centered in large measure on the achievements during 1973—or perhaps we should say the events during 1973. All agree that it was a tumultous year with our domestic and environmental concerns largely overshadowed by unprecedented political events at home and abroad.

1973 was to be the year when the momentum of the environmental movement began to take us around the corner in cleaning up the air and the water. Our arsenal of regulatory tools for insuring product safety and sound disposal practices was to be expanded. And a degree of harmonization was to be achieved between economic progress and environmental controls.

But this was not the case. Energy concerns threatened to reverse past environmental gains. Congressional attention was diverted from the details of environmental legislation. And perhaps most unfortunately the influx of top young talent into the environmental picture seemed to slacken.

However, environmental milestones were far from lacking during 1973. For example, in the area of toxic substances:

- The chemical industry is still reverberating from the Department of Labor's stringent interim standards for handling 14 carcinogens, including several of considerable commercial importance.
- FDA banned the use of DES as a feed additive over the strong objections of the cattle ranchers.
- EPA's promulgation of final air emission standards and proposed water effluent standards for toxic pollutants are causing major adjustments in manufacturing practices at many facilities.
- Promulgation of final leaded gasoline regulations culminated several years of effort to address the severity of the problem of lead inhalation and human health.
- Discovery of high levels of asbestos fibers in the Duluth water supply has catalyzed a large array of technical talent to address what could turn out to be either a sleeping giant or a false alarm of major dimensions.
- The tussock moth outbreak on the West Coast highlighted the environmental and economic "disbenefits" resulting from the ban on DDT.
- Finally, the National Center for Toxicological Research in Pine Bluff, Arkansas, became a viable operation that is making its mark in the regulatory world.

THE ISSUES FOR 1974

While the number and diversity of issues in the environmental field continue to grow, many of the most important questions to be addressed in the immediate future in my specific area of concern are the well-known "old chestnuts". Traditionally, we tend either to take these issues for granted or skirt them because of their difficulty. In either case we then focus on other questions which are also important but which could be irrelevant if our fundamental approach is not sound. Let me cite four of the "old chestnuts" which are currently near the top of our list.

ological Testing and Standard Setting: Can We D better?

Emblazoned in laws and in the Federal Register are standardized approaches to a very complicated science—standardized approaches that date back many years and, having gained a type of legal status, seem almost immune from scrutiny and revision. As an engineer I should feel comfortable in surrounding the biological sciences with accepted quantifiable approaches and easily defined safety factors, but I am not. In my view, a thorough review—initially by the scientific community itself—of the currently accepted approaches to generation and interpretation of test data is needed.

In this regard, EPA recently proposed a numerical standard for the carcinogen benzidine based on the concept that in determining the standards, the level of risk which is acceptable must be considered in the light of the benefits derived from the chemical. Derivation of this level of risk requires types of test data not ordinarily generated by toxicologists, thus suggesting a significantly different approach to testing carcinogens, and perhaps other chemicals as well.

In large measure the issue revolves around how the scientist packages the toxicological data for the decision-maker. If the scientist structures the

experiment and packages the data to derive simply a "safe" level for chemical exposure, then the decision-maker has only one option, and all other factors become irrelevant. The scientist has in fact assumed responsibility for consideration of the total impact of a regulation on society. On the other hand, if the scientist presents several options, with explanations of the health and environmental implications of each, then the decision-maker can indeed take into account a wide range of social and economic implications at different levels of chemical exposure.

Risk/Benefit Aspects of Toxic Substances: The Theorist or the Pragmatist?

Even though toxic substances are by definition dangerous to health or the environment, there seems to be general agreement that in developing control strategies some balancing of risks and benefits is in order, as reflected in the EPA action on benzidine. In the past, elaborate cost/benefit models have frequently had little operational relevance. At the same time we must do better than those past efforts that tend to focus only on the short-term, direct costs of environmental controls which are susceptible to quantification.

Perhaps the most formidable task is estimating the incremental gains to society—or the reduction of risks to society—by decreasing the level of a toxic substance entering the environment. Human poisoning, fish kills, and flora destruction can of course frequently be related to specific discharges. But these near-term, easily isolated incidents which can be used to correlate discharge levels with economic and social impact are the exception rather than the rule. A second problem is to estimate how much the level of exposure will be reduced by a specific control measure. Even if good monitoring data exist concerning current exposure levels, to project ahead the impact of a proposed measure is difficult indeed. And finally, of course, is the cost of the control measure, which usually involves much more than simply purchasing control devices. For example, in response to the Department of Labor restrictions on carcinogens, one company was forced to replace the carcinogen with another intermediate chemical which turned out to be far more cost/effective for the particular process. Had it not been for the regulation, and subsequent R and D effort by the company, this cost-saving innovation would still be lying dormant.

What should be the approach to risk/benefit analyses? With regard to the known problem substances, I suspect that in the short run we will do little better than weighted checklists to be used as general guidelines for at least surfacing some of the concerns before decision-making time. Case studies of specific past decisions should be particularly helpful in this regard. In the longer term, I don't know if a more objective approach can be developed that is broadly applicable to balancing risks and benefits.

However a far more difficult problem faces us in answering the question: "How much is society ready to pay to search out other problem substances before they emerge as problems on the immediate horizon?" Or "What should be the cost of early warning?"

A Generalized Approach to Control Strategies for Multimedia Pollutants: Reality or Fantasy?

A number of the most troublesome toxic pollutants enter the environment from many sources, follow multiple routes through the environment, and come to rest in a variety of places. Studies have illustrated many of the complexities of movement and fate of pollutants. Such studies were particularly helpful in addressing the lead issue, as one example.

Can there be a generalized approach to control strategies for a large number of toxic pollutants with multimedia characteristics? Perhaps the behavioral and use idiosyncrasies of different chemicals require completely different approaches to the formulation of control strategies. Two of our most relevant experiences to date in developing control strategies have been the attempts to control selected toxic pollutants under different sections of their air and water legislation. These single media approaches to control strategies clearly underscore the difficulty of generalized approaches.

Obviously, there should be some correlation between the controls that are selected to mitigate the problem associated with a specific chemical and the portion of the problem that these controls actually address. Similarly, in considering the total allowable body burden for a chemical, there should be some consistency in allocating the total among individual control measures. But can we be much more specific in generalizing approaches, say, to three of the most widely discussed toxic chemicals, namely, cadmium, mercury, and PCBs? It is difficult to identify the common aspects of cadmium-coated screws, mercury-containing dental amalgam, and polychlorinated biphenyls used in transformers, which would fit into general control strategies. Once

again, at least as an interim step, I would argue for case studies as providing a background of experience in addressing future approaches to multimedia pollutants.

An Operational Early Warning System: Is It Practical?

The need to identify and remedy problems before they take their environmental or health toll seems axiomatic. But can this be done on more than a token basis? Clearly, this question goes to the heart of this Conference.

Several approaches to problem identification seem reasonably clear:

- Gatherings of experts, such as this meeting, and also organized on an industry-by-industry basis.
- Review of past incidents to identify early warning indicators.
- Current awareness systems to identify reported and unreported incidents involving toxic substances.
- Forecasts of market and economic trends and their impact on the future mix of products and activities of the chemical industry.

Many of you have promoted activities in these areas for some time, and we will be joining you in all of these areas in the months ahead.

What is most needed now? Better use of existing early warning systems? Bigger and better systems? More systematic orchestration of the multiple systems? I hope you will clarify these questions.

However, there undoubtedly will remain a major gap between problem identification and preventive action. Bridging this gap is particularly difficult for a bureaucracy that is basically reactive to immediate problems—and reactive in a very short-term mode. Thus, persuasive argumentation supporting the action recommended by the early warning network is essential.

Even assuming that false alarms have been separated from potentially serious problems, it will be difficult indeed to impose restrictive measures before the fact largely on the basis of unsubstantiated data. In my view, unless there is extensive cooperation on the part of industry in heeding the early warning signals—cooperation reflected in a great deal of restraint on a voluntary basis—the products of the best conceived early warning systems are not likely to make a major impact on more than a small handful of a much larger array of potential problem substances.

THE CHEMICAL INDUSTRY AND POLICY ISSUES

The industrial representation at this Conference is encouraging. Indeed, in recent months a number of companies have shown considerable leadership in enhancing product safety, in improving the environmental compatibility of manufacturing processes, and in expanding R and D efforts to further clarify the risks of chemical activities.

For our present purposes we are interested principally in those manufacturers and processors who introduce chemical changes into their products. The following characteristics of this sector of industry—excluding the food, drug, cosmetics, and pesticides segments—seem particularly relevant:

- The annual value added to products is in the range of $110 billion, about double the level ten years ago.
- About 20,000 chemical products are in commerce with an additional 500 chemicals being added annually.
- More than 80 percent of sales is concentrated in several dozen companies but there are hundreds of additional small manufacturers.
- A large percentage of net income—ranging from 20 to 50 percent—is usually reinvested in R and D.

A number of policy considerations of particular concern to industry permeate a regulatory approach to this sector of industry, from early warning to restrictions. Some of these concerns are:

- The disincentives to R and D inherent in some types of regulatory actions could blunt the technological thrust of the industry.
- The configuration of the industry (e.g. large and small manufacturers, specialized and diversified firms) could be affected by regulatory actions which are more painful to certain types of companies.
- Regulatory actions undertaken unilaterally by the United States could affect the competitiveness of our products at home and abroad.

This does not mean that environmental actions should not affect economic interests, for environmental control is not free. However, we should recognize that individual actions—and also aggregated actions—can have many secondary and tertiary effects which may be far more significant than the more obvious primary effects. The key question of course is whether the environmental gains from regulatory actions are commensurate with any adverse economic and social impact--a question that is easy to ask but difficult to answer. In any event, we must treat early warning signals in a responsible fashion lest the potentially affected parties seek to bury the signals out of concern that they will not be handled responsibly.

LOOKING AHEAD

Clearly Washington's preoccupation with non-environmental issues will continue to detract from the high level attention devoted to toxic substances in the months ahead, particularly on Capitol Hill. For some of the newer programs this may be a fortuitous development which will allow us to do a better job in planning long range activities, even though all of us would like to move ahead with operational activities.

During 1974 we should continue to press forward vigorously on all fronts, recognizing that regulatory actions will be more difficult amidst the general skepticism as to the importance of environmental control being expounded in some quarters. There is no reason, however, why we should not make great strides in many of the essential supporting activities. There is general agreement on the importance of increased efforts to clarify the need for, character of, and impact resulting from steps to prevent and mitigate environmental problems. Thus, I would characterize 1974 as a year of transition—a year between a period of talk and rhetoric about the need for new regulatory approaches to reduce risks associated with toxic substances and a period of accelerated action to address these risks. 1974 should be a year of coalescing ideas and energies, a year of engaging all the affected parties, and a year of setting the stage for a sensible long-term effort in dealing with multimedia pollutants.

In future years, more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently suspected effects.

Even though in a few years the emission stacks and effluent pipes will be largely plugged, and hopefully sensible land disposal of hazardous wastes will be required, more people will be exposed to more chemicals in more situations—exposure from contaminants, non-point sources, direct product contact, and generally unattributable buildup of chemicals in the environment. I am confident that society can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly in anticipating and remedying toxic substance problems through its governmental and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts—which would be a tragedy for us all.

Thus, the challenge to early warning is clear. It is a challenge that will

- prioritize and focus the concerns of Government and of society on those chemical/biological interactions that require particular scrutiny in the months and years ahead;
- provide the time needed for sluggish governmental, industrial, and commercial mechanisms to take almost unprecedented anticipatory actions; and
- instill a sense of public confidence that the products of chemistry—both new types of goods and substitute materials for rapidly dwindling natural materials—can be made compatible with an increasingly fragile biosphere.

EPA PROGRAM INTERESTS AND TESTING

Meeting on Environmental Cooperation
U.S.—European Communities
Washington, DC
February 7, 1974

Interest in toxicological and environmental testing is shared by all EPA programs. Test results often signal those substances that should be prime candidates for regulatory control. Also, test results frequently are the starting point for setting numerical standards and tolerances.

TESTING REQUIRED OF INDUSTRY

Three EPA offices are currently involved in developing and articulating requirements for industrial testing for health and environmental effects. Test data are required to determine the need for product controls and, when appropriate, to set specific numerical standards. It seems clear that there should be a degree of consistency in our overall approach to industrial testing as reflected in the ground rules established by these programs. Also, to the extent possible, consistency is desirable among the approach of EPA and the approaches of other agencies, such as the Food and Drug Administration and the Consumer Product Safety Commission.

For many years, registration of pesticides has required the submission of industrial test data. Over the years the data requirements have been articulated in a variety of formal and informal documents, but only recently has there been an attempt to consolidate past fragmented requirements—including undocumented requirements—into a coherent Agency approach. These requirements relate to both product safety and product efficacy. Within the next year, we hope to publish guidelines which will set forth in some detail testing requirements in support of applications for pesticide registration.

Under the Clean Air Act the Agency can require the testing of fuel additives for health and environmental effects. This is a new program—in a somewhat virgin area—and we are only now attempting to develop such test requirements. Perhaps, the most difficult problem is specifying the composition of the substance to be tested. We are primarily interested in the inhalation of exhaust products which are the result of a variety of complicated chemical reactions.

A third program, which is still being borne, will provide the Agency with authority to require testing of industrial chemicals suspected to pose a risk to man or the environment. This proposed new authority, which is currently pending in the Congress, covers a much broader variety of activities than existing authorities. The two principal emphases will probably be on testing for chronic health efforts and on testing for environmental effects. These of course are the most uncertain areas at present.

POLICY CONCERNS IN DEVELOPING REQUIREMENTS FOR INDUSTRIAL TESTING

There are a number of policy issues common to these programs that we are currently addressing. Among the more important concerns are the following:

— *Extent and Costs of Testing:* How much testing is enough? At what point will testing costs discourage R & D on new products that may prove to be safer than currently available products? Will testing requirements add intolerable delays before marketing a product?

— *Flexibility in Test Requirements:* How specific should be the test requirements set by Government? Should industry be afforded a degree of flexibility in determining the details of testing and in suggesting alternative approaches to those specified by Government? How can test requirements allow for advances in the state-of-the-art without being subjected to constant revision? Will over-standardization of test requirements dampen innovative R & D on the part of industry?

— *Status of Protocols:* What status should be accorded to protocols developed by the Government or with Governmental support, by professional societies, and by industry itself? Should such protocols be mandatory, be illustrative, or simply provide guidance?

— *Trade Secrets:* Under what, if any, circumstances should safety data developed by industry be considered trade secrets? Should there be a difference in the confidentiality aspects of safety data submitted by industry for chemicals already in commerce and for chemicals still in the R & D stage?

— *Sharing of Costs:* Under what circumstances should test costs be shared among several manufacturers of the same chemical? How should the costs be shared? Can cost sharing be reconciled with anti-trust laws? What role should the Government play in arbitrating the details of cost sharing?

GOVERNMENTAL SUPPORT OF TESTING

In our view, the principal responsibility for testing chemicals that are in commerce or will enter commerce in the near future resides with industry. The Government's primary role is to insure that this testing is adequate and that the test results are considered in an effective way in assessing the safety aspects of the chemicals. Given this role of Government, several specific types of concerns require Governmental support of testing activities:

— It may be necessary to verify in advance the feasibility, adequacy, and reliability of proposed tests to be required by industry.

— It may be necessary to confirm or supplement test data provided by industry.

— The urgency or complexity of potential environmental problems resulting from a chemical may require a Governmental response based on tests that are initiated without delay.

— It may not be possible to identify the commercial organization which has the logical responsibility for testing a specific chemical, such as in the case of chemical contaminants of unknown origin.

There are at least two other reasons why a Governmental regulatory agency supports testing activities. Laboratory scientists actively engaged in testing activities are essential members of the Governmental teams that develop specific testing requirements for industry. Their input is essential to broaden the perspective of the desk bureaucrats. Secondly, the Government has traditionally assumed responsibility for stimulating advances in the state-of-the-art. These efforts include support for new approaches to testing, refinement of existing approaches, and demonstration projects that can be adopted by industry. At the same time, as specific problem chemicals emerge, it is important that overzealous Government scientists—eager to clarify the uncertainties—not launch testing efforts under the guise of research that pre-empt the responsibilities of industry.

Of particular interest are the rapidly developing programs of the recently established National Center for Toxicological Research in Jefferson, Arkansas, which is jointly supported by EPA and the Food and Drug Administration. This facility is devoted to improving testing methodologies related to chronic effects with particular attention to the shape of the lower end of the dose/response curve. Funded at a level of about $15 million annually, and emphasizing experiments involving very large numbers of animals, this facility should have a major impact on testing approaches throughout the world in the years to come.

THE USE OF TOXICOLOGICAL DATA

Recently, EPA proposed a numerical effluent standard for the carcinogen benzidine. The derivation of this standard brought into sharp focus the inadequacy of current approaches to testing for the purposes of standard setting, both for carcinogens and for other chemicals. In my view the traditional approach of determining a no-effects level in animals and then extrapolating to human effects via safety factors is not adequate in many cases, particularly when there are questions as to whether there are thresholds and whether irreversible effects are involved. On the other hand, describing the risks in terms of probabilities of incidents through existing statistical extrapolation techniques—such as was done in the case of benzidine—and then balancing these alternative risk probabilities against the costs of the environmental control may not offer the optimal approach. In any event, we are looking forward to an initial confrontation of our biostatiticians and our toxicologists on this very issue during the next several weeks.

In large measure the issue revolves around how the scientist packages the toxicological data for the decision-maker. If the scientist structures the experiment and packages the data to derive simply a "safe" level for chemical exposure, then the decision-maker has only one option, and all other factors become irrelevant. The scientist has in fact assumed responsibility for consideration of the total impact of a regulation on society. On the other hand, if the scientist presents several options, with explanations of the health and environmental implications of each, then the decision-maker can indeed take into account a wide range of social and economic implications at different levels of chemical exposure.

ENVIRONMENTAL CONCERNS BEYOND THE WORKPLACE

Working Group on Toxicity of
Vinyl Chloride-Polyvinyl Chloride
The New York Academy of Sciences
New York, New York
May 11, 1974

During the past several months vinyl chloride has awakened all elements of the environmental community to the presence of the plastics industry. In some respects it is fortunate that we have been alerted in a rather dramatic fashion to the need for greater attention to this important segment of our industrial base which will surely continue to expand in the years ahead. While this symposium is directed to the existing and potential risks involved in the manufacture, distribution, and use of vinyl chloride monomer (VCM) and polyvinyl chloride (PVC), many of the types of considerations and uncertainties that punctuate these deliberations undoubtedly characterize a far broader swathe of concerns over chemicals in general. Hopefully, we can extrapolate from our current experiences with VCM and PVC in identifying problems with other potentially important commercial chemicals early in their embryonic stage and thus minimize the economic dislocations attendant to corrective actions.

Unfortunately, the proposed Toxic Substances Control Act has been lodged in a Joint Committee of the Congress for ten months. Thus, a very powerful tool for addressing the vinyl chloride problem, and similar problems with other chemicals, in an adequate manner is not available to the Federal Government. We must rely on other statutory authorities and on the power of persuasion in our efforts to insure that our population is not being unnecessarily exposed to concentrations of VCM and other chemicals used in connection with VCM. It is particularly distressing that until this statutory authority is on the books, the Federal Government will not be equipped—in terms of experienced personnel and supporting resources—to grapple with the intricacies of this type of toxic substance problem in a manner which will insure full attention to the balancing of risks and benefits.

Today I will report to you on the preliminary investigations undertaken by the Environmental Protection Agency during the past three months. We are still several weeks away from reaching even tentative conclusions as to what additional steps, if any, should be taken by the Agency concerning VCM/PVC activities. Our monitoring data are not yet in hand. Similarly, our analytical studies are not yet completed. Nevertheless, we are pleased to share with you some of our initial thoughts. We will welcome your comments on the efforts to date and on further steps which are necessary. In this regard, the prioritization of our efforts is particularly important in view of the speed with which this problem is evolving and the limitations on our resources.

At the outset it is important to underscore that the progress made to date would not have been possible without the extensive cooperation of other federal agencies, industry, and environmental groups. We have profitted greatly from our discussions with these organizations, through our on-site industrial visits, and through constructive suggestions that we have received.

EPA REGULATORY AUTHORITIES

To date EPA has exercised its authority in the pesticides area to suspend the use of vinyl chloride as a propellant in all pesticide products registered for indoor use in homes, food handling establishments, and other enclosed areas, with a mandatory recall of stocks in the channels of trade. In addition, in response to the Agency's request, all registrants of pesticides which are used outdoors have agreed either to withdraw their registrations or to amend them to provide for the substitution of another propellant in their products.

We are currently investigating what regulatory actions, if any, are needed with regard to air emissions, water effluents, and solid waste disposal at facilities involved in VCM and PVC activities. In addition the Agency has responsibility in the areas of drinking water standards, ocean disposal, and municipal waste disposal—all areas of some relevance to the VCM/PVC concerns.

As previously mentioned a principal authority which is currently missing is the Toxic Substances Control Act. The requirements for reporting of industrial production data envisaged in the Act would enhance our knowledge of the types and extent of different uses of VCM. The testing provision would enable us to obtain much needed data—and particularly data on toxicity and persistence—for assessing the risks associated with low concentration levels of VCM, including those levels that are likely to persist beyond the workplace. The proposed regulatory provisions would provide a mechanism for addressing those

products using VCM not now subject to regulation under other laws. Also, if considered appropriate, steps might be taken to limit the amount of unreacted VCM in certain PVC products which may eventually migrate out of these products to pose an unnecessary risk.

THE MATERIALS BALANCE

EPA's initial concern in this area centered on reports in February of a materials loss of six percent in the PVC production process. Our detailed investigations indicate that these initial reports were in the correct range. Clearly, the percentage of losses will vary with the type of process, the age of the plant, the level of technology that is employed, and manufacturing practices. However, there is no doubt that in the United States substantial amounts of VCM—probably exceeding 200 million pounds annually—and large quantities of PVC—probably exceeding 50 million pounds—are being discharged into the environment during the PVC production process. Most of the VCM escapes directly into the atmosphere as air emissions, with lesser amounts dissolved in water effluent streams and entrapped in sludge and solid wastes. PVC losses occur as particulate in air emissions, suspended solids in water effluents, and components of solid wastes.

Clearly, a principal area of VCM leakage is associated with the operation of the polymerization kettles, including losses when they are opened for recharging, cleaning, or sampling. Other losses occur during the transfer of VCM from tank cars to storage, during the drying process, and from leaks at a variety of valves, flanges, and pump seals throughout the process. Polymer losses are similarly distributed among a variety of activities including dust collector losses, disposal of oversize particles, and sampling losses. Our estimates indicate that losses for a typical suspension process vary from four to eight percent. In this regard two aspects are particularly significant: there are a variety of PVC processes with differing problems and control possibilities and in every case the number of potential leakage points is very large.

For economic reasons and in view of the fire hazard from VCM industry has always been concerned with reducing its losses down to a point. Now some plants are taking steps to reduce these losses further in view of worker and environmental concerns. We understand that the tightening up on maintenance and housekeeping activities can indeed have a significant impact, and several PVC plants reportedly are now operating close to the four percent level for total losses.

The data needed for conducting material balance analyses during VCM production and PVC compounding and fabrication processes are less readily available. However, we do not believe that these activities pose as serious an environmental concern beyond the fence line of the plant, at least at the present time, as the polymerization process. At the same time in the absence of constant vigilance VCM losses to the atmosphere during the latter phases of the VCM production process and during transfer to and from storage can be significant. Also, throughout the process there are many seals and valves which inevitably lead to leaks. With regard to compounding and fabrication, unreacted monomer is inevitably associated with the polymer following the polymerization process. In some cases this monomer concentration reaches 7000 ppm although a more representative level probably is in the range of 500 to 1000 ppm. During the mixing and heating processes in the compounding and fabrication plants, some of this VCM undoubtedly escapes into the environment. Now, in efforts to reduce further the level of unreacted VCM in the final product many companies are introducing new techniques which increase the migration rates during this phase of production.

THE NEED FOR EPIDEMIOLOGICAL AND TOXICOLOGICAL STUDIES

Since some elements of our population in addition to the plant worker are being exposed to some level of VCM, we must address the question: What is the risk of such exposure?

In considering non-worker populations, we are confronted with a host of new unanswered questions. How relevant to this concern are the data generated for estimating worker exposure risks? Can meaningful extrapolations be made from toxicological tests at relatively high dose levels to the lower levels of the dose-response relationship? Can realistic extrapolations be made from intermittent exposure, which characterizes the past and present toxicological and epidemiological investigations (e.g. eight hours per day, five days per week) to sustained exposure at the same dose levels or at lower levels? Are synergistic effects that result from exposure to other chemicals as well as VCM influencing the worker's response to VCM, and are there similar opportunities for such synergism within a non-worker population?

There are not sharp answers to these questions, and indeed they go to the heart of many of the fundamental uncertainties of the biological sciences. To date the epidemiological and toxicological data

that have been generated have been directed almost exclusively to concerns over workers. This is the data base that we in EPA presently have available. I don't think that anyone is more aware of its inadequacy than are those of us responsible for regulatory actions based on this data. Unfortunately, we often have no choice but to make judgmental decisions using whatever scientific information is available.

Other reports presented at this symposium review past, current, and future studies directed to VCM. While they will undoubtedly be helpful to our assessment of the environmental problem, from our point of view that are clearly not adequate in improving the basis for estimating non-worker risks. Let me cite three examples of the types of studies which appear to be needed:

- Epidemiological investigations of populations near chemical plants that are likely to have been exposed to low ambient levels of VCM over a prolonged period of time. It is the responsibility of industry to support such efforts which will help clarify whether manufacturing activities pose a risk to neighborhood residents. At the same time we recognize the complexities involved in designing and carrying out such studies, the advantages of drawing on governmental experience in this area, and the prototypic nature of such an undertaking. Therefore, it seems likely that EPA will be prepared to participate in such efforts along with industry and other interested parties.
- Toxicological tests at appropriate dose levels, with a sufficiently large number of animals, and with appropriate exposures to provide the basis for meaningful conclusions concerning the likely health effects of VCM in ambient air near chemical plants. Such tests are clearly the responsibility of industry. Indeed, industrial responsibility for the testing of the safety of its products is a basic tenet of the Toxic Substances Control Act. At the same time, we are aware that some industrial firms are concerned about the possible inadequacy of commercial test facilities to accommodate the needed tests. Therefore, if necessary, the National Center for Toxicological Research, which is supported by FDA and EPA, is prepared to work with industry toward suitable arrangements for utilizing available buildings in Jefferson, Arkansas.
- Research on animals and *in vitro* experiments to help clarify the toxicological significance of impurities in VCM, synergistic effects due to exposure to other chemicals in addition to VCM such as vinylidine chloride, and metabolic reactions induced by VCM. Government, industry, and academia all have responsibilities in this area, and EPA is currently considering specific steps that might be taken to contribute to advancing the frontiers of our knowledge.

MONITORING, PERSISTENCE, AND MIGRATION STUDIES

We are obviously concerned about current and future background levels of VCM in the air and in the water throughout the country. Our more immediate efforts, however, are being directed to determining ambient and peak levels near chemical plants.

Recently, we initiated a nationwide sampling and analysis program to determine, at least in a preliminary fashion, the VCM levels in ambient air and in water and semi-solid effluents at about ten PVC plants. These activities are currently underway, and we hope to have the results within several weeks.

As a precursor to this nationwide effort, several weeks ago we conducted a preliminary monitoring program at the B. F. Goodrich plant in Louisville using inadequately tested sampling and analysis methods. At that time VCM levels were detected of 1 to 2 ppm in the ambient air outside the plant, 2 to 3 ppm in the primary water effluent, and 100 to 200 ppm in the sludge at the plant site. However, these numbers could be in error by as much as an order of magnitude due to the pioneering nature of the effort, and no conclusions should be drawn at this time.

During the past several weeks we have made a major effort to develop credible and standardized sampling and analysis procedures, building on this initial experience. Our current monitoring efforts are based on this recently improved methodology. The limit of detection for our current technique is approximately .06 mg/liter in water and .06 ppm (volume/volume) in air. However, when vacuum cans are used, the detection limit is .2 ppm because the gas sample must be diluted. The technique we are using is now publicly available with the hope that our efforts toward standardization will lessen the chaos characterizing current monitoring efforts of several federal agencies and industry.

While the near-term objective of these monitoring efforts is to gain a limited perspective of the levels of VCM near PVC plants, we should also learn more

about the persistence of VCM in air and water from our measurements. Samples are to be taken during daytime and at night, and there undoubtedly will be a range of temperature and humidity conditions. However, we have not structured the measurements with research as a principal objective, and we will not be able to quantify persistence characteristics with any degree of precision.

Limited laboratory experiments are also being attempted to clarify persistence characteristics of VCM. Related to our decision to suspend pesticide sprays containing VCM, one laboratory test showed that in an unventilated and unlighted chamber, less than one percent of the VCM initially persent was dissipated after four days. Current efforts are directed to clarifying the rate of retention of VCM entrapped in water effluent streams, as well as further work to understand the effect of light, heat, and moisture on VCM in air.

There has been considerable discussion of the amount of unreacted VCM monomer remaining in PVC and the rates of migration out of the PVC. Many companies are now seized with this problem, and I suspect the number of samples being taken to determine VCM concentrations and migration rates has increased considerably in recent weeks. We do not know whether such migration from finished products contributes significantly to background levels of VCM, but as you are aware FDA is seized with several aspects of this problem directly related to food. Should there be high levels of VCM background in the environment, then our concern over all sources of VCM—including migration from many products—should intensify.

In all of these areas industry has a major responsibility for determining and alerting the public about the behaviour of its products. I would hope that in the months and years ahead industrial monitoring efforts at the fence line will increase dramatically; persistence will become a key concern; and the ultimate fate of chemicals will be less uncertain. Already some chemical establishments have rather broad sampling and analysis programs, and as a direct result of VCM concerns, others are also making new efforts in this regard.

At the same time EPA has a responsibility to help insure the adequacy of the national effort in keeping abreast of the chemical cross-section of our environment.

CONCERNS OVER DISPOSAL OF PVC

While we tend to lump all types of PVC into one category, I am sure you are aware of the variances in the chemical and physical properties of different grades of PVC. Also, end products made from PVC include a variety of other chemicals which are added throughout the production cycle.

To date EPA's principal concerns relating to PVC have been directed to possible problems attendant to its disposal—either in incinerators or landfills. We have not investigated in depth any of the special problems associated with inhalation or ingestion of low concentrations of PVC particulate.

With regard to incineration, HCl is a primary product of concern. Also, toxic metals may be present as additives and thus cause inhalation problems, either as metal or oxide vapors.

Landfill disposal operations have traditionally assumed that PVC is stable with little likelihood of biological degradation or undesirable leachates. Taking a long-term perspective these assumptions seem clearly overly simplistic, and we should address in greater depth problems attendant to the disposal of plastics. Experiences in the tropics, for example, have demonstrated the effect of bacteria on PVC which has not been specially treated for use in humid areas.

THE RISKS, THE BENEFITS, AND THE COSTS

The current problems with VCM have brought into sharp focus the practical aspects of balancing the risks and benefits associated with commercial chemicals. The costs involved to reduce these tasks substantially may be formidable—or indeed may be prohibitive. The aspect which is perhaps the most troublesome goes to the heart of this meeting—What is the risk now and under alternative regulatory approaches?

In the years ahead more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently suspected effects.

As these realities of the chemical age unfold, there must be a far greater sophistication in approaches to responsible regulation. Hopefully, we will develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

CHEMICALS, THE ENVIRONMENT, AND REGULATION

Quality Assurance Seminar
Borden, Inc.
Columbus, Ohio
June 5, 1974

About 20,000 chemical substances are commercially produced and used in the United States, with 500-700 new substances entering commerce annually. They find a wide variety of uses as industrial chemicals, in consumer products, and in specialized uses such as drugs, food additives, and pesticides. We estimate that about ten percent of U.S. industry is directly involved in introducing chemical changes into its products. This is the sector of industry of interest.

The problems presented by the presence in the environment of some chemical substances are all too well known (e.g. mercury, lead, asbestos). Others are believed to pose a latent health or environmental threat, while the effects associated with many of the remaining chemicals, acting individually or synergistically, are almost completely unknown. However, it seems clear that the problems associated with the presence of many chemical substances in the environment—such as food and drinking water contamination, destruction of biota, and water and soil degradation—will undoubtedly continue to grow in number, severity, and complexity in the years ahead.

Some of the hazards associated with chemical substances have been recognized and are controlled by the Government, e.g. pesticides and drugs. Other aspects of the toxic substances problem have only recently been identified, and appropriate regulatory measures do not yet exist. Still other pieces of the problem have yet to be identified. Many gaps remain in understanding why, how, and when a substance can have a negative impact on health or the environment, and how best to control or prevent such hazards.

Thus, the concern of EPA with toxic substances is two-fold: Identification and assessment of the risks associated with the manufacture, distribution, use, and disposal of chemical which could adversely affect health and environmental quality; and practical steps, including regulatory actions as appropriate, to prevent or mitigate the problems posed by such chemicals.

The risks associated with toxic substances are related to many factors including the size of the dose, duration of exposure, form of the substance when released, and presence of other substances that also contribute to environmental stresses. Problem assessment is further complicated by the many unknowns that surround the characteristics and behaviour in the environment of most toxic substances, including such aspects as persistence, degradation, accumulation, and movement among environmental media. Good information is not readily available concerning levels, distribution, and trends in the environment of many substances of concern. With regard to the adverse effect of toxic substances, testing approaches for measuring chemical properties and acute toxicity are reasonably well developed. However, similarly well developed test methods for determining chronic toxicity and for estimating environmental impact are not in hand.

The success of past efforts to reduce these deficiencies and uncertainties has been spotty. Monitoring systems generally lack the capability to relate effects to specific substances, and research efforts are only now beginning to address many core issues. Lack of effective integration of the many Federal monitoring and data systems further impedes rapid progress.

In seeking to control specific toxic substance problems, the Government can draw on three types of regulatory authorities:

- Consumer protection statutes which have as their primary mission the prevention of acute risks to human health. They, however, do not address problems of environmental protection nor human exposure to toxic substances through environmental routes.
- Media-oriented statutes which focus primarily on problems at the point where they become environmental contaminants, typically, after they are manifested at the end of an outfall pipe or smokestack.
- Statutes dealing with a particular phase of the existence or use of a toxic substance such as risk to workers, transportation-related accidents, and use of pesticides which are toxic by design.

Pending legislation is directed to enabling EPA to deal with problems which do not currently fall within the existing regulatory framework, and particularly with regard to drinking water standards, disposal of toxic wastes, and problems associated with use and distribution of chemical

substances. In addition, EPA would have authority to control certain types of problems before they appear in the environment. In the absence of such legislation, efforts to cooperate with industry on a voluntary basis in addressing specific problems beyond the reach of current authorities must continue although the results of past efforts have been somewhat uneven.

There are many interfaces among existing regulatory authorities, and the passage of new legislation will further extend the options for addressing specific problems. Implementation of the air and water acts, for example, has involved selection of the most appropriate legislative provisions within these acts for addressing problems of toxic substances in addition to development of criteria to determine if regulation is needed or appropriate under specific provisions. Another example is the control of the use of certain pesticides under the pesticide act while point source discharges of these same chemical are being considered for control under the water act. Further complicating effective choice of regulatory options is the tendency to search for problems to be controlled under specific authorities rather than searching for the authorities that will most effectively control problems. This approach of controlling the "accessible" aspects of the problem, which may or may not be the "critical" aspects, can hamper efforts to cope with the core of the environmental and health risks posed by manufacture, use, and disposal of toxic substances.

Central to consideration of regulatory options is the balancing of the risks with the benefits related to the action. The diversity of the tradeoffs make this a formidable task. For example, the benefits from employment of workers in chemical plants must be balanced against occupational risks; U.S. competitive ability in world markets weighs against environmental testing costs or requirements of expensive effluent or emission controls; and quality of life benefits from chemical substances bear on the degree of risks which can be tolerated. Restrictions placed on existing activities will affect past investments and established patterns of commerce and employment. With respect to those chemicals which have yet to be offered for commercial use, barriers to market entry could be created through pre-testing and screening requirements. If research and development of new chemicals becomes so difficult that it is no longer profitable, the advantages to society, in terms both of new products and development of less toxic alternatives to existing products, are lost. In short, environmental protection is not free. Care must be exercised in assessing the impact of corrective actions on the direction, configuration, and diversity of the chemical industry as well as on the benefits to society of chemical products.

TOXIC SUBSTANCES CONTROL ACT

The proposed *Toxic Substances Control Act* would give EPA new authority for (a) information acquisition, and (b) restrictive actions. EPA could require testing of chemical substances (both existing and new) which are suspected to pose unreasonable risks and also require other information from manufacturers including the name of the substance, chemical formula, amounts produced, actual or intended uses, and known by-products. EPA could then restrict the use and distribution of chemical substances found to pose unreasonable risks. The Agency could prescribe the amounts of a chemical which may be sold to processors, limit the type of processor to whom it may be sold, restrict the amount a given type of processor may use, or limit the sale or manner in which a substance may be used, handled, labelled, or disposed by any person.

This new authority is important from two standpoints. First, the Federal Government is given direct authority to restrict substances presently in commercial use that are known to cause health or environmental hazards, and when effects information is lacking, to require testing of the substance by the manufacturer to assess human or environmental impact. Second, for substances not yet in commercial production, the Agency could require premarket testing and review of chemicals suspected to be hazardous. The Agency would have the opportunity to assess the risks before the new substances are commercially produced and to take appropriate regulatory action to prevent toxic incidents.

Given the extensive scope of the legislation, the number of areas of initial emphasis will depend to a significant degree on the staff and resources available for implementation activities. In selecting areas for priority attention consideration should be given to Congressional mandates, severity and urgency of existing problems which can be alleviated by the new authority, opportunities to reduce future problems of major dimensions, and necessity for establishing long-term viability of implementation procedures.

While the final version of the legislation may influence the choice of initial activities, it seems

clear that the following activities should be high on the agenda for early attention:

— Elaboration and articulation of the criteria or sets of criteria to be used in weighing risks versus benefits, and in determining when regulatory action is needed. Clear understanding by both industry and Government of the ground rules for restrictions is essential to the viability of industrial R & D activities.

— Determination of the character and scope of initial testing requirements, including the possibility of umbrella testing requirements for a broad range of chemical classes, and identification of specific chemicals or classes of chemicals of particular immediate concern. While the selection of substances covered by the standards for test protocols that are initially promulgated will in large measure reflect intuitive judgments concerning likely hazards and inadequacy of current data, concurrent work is needed to provide a basis over the longer term for selecting areas of concern.

— Development of regulations setting forth timing, coverage, content, and format of the reporting requirements for chemical manufacturers and processors, including both annual reporting and premarket notification.

— Establishment of a data system for handling the industrial reports and test results that are submitted. Experience in the pesticide area underscores the importance of early attention to establishing efficient and decision oriented procedures to be effective when the first reports arrive.

CHEMICALS AND CORPORATE RESPONSIBILITY

A fundamental tenet of the Toxic Substances Control Act, and indeed of the entire federal approach to environmental control, is that industry has a primary responsibility to insure that (a) its products do not pose health or environmental risks—direct or indirect, immediate or delayed, and (b) the associated manufacturing activities do not contribute to environmental degradation. Shorthand characterizations of these areas of responsibility are product safety and pollution control.

As you well know, many of our major chemical companies have long experience in dealing with FDA in the area of product safety. In some cases FDA is quite precise as to safety requirements; other determinations are made on a case-by-case basis in consultation with the concerned company. In general, considerable care is taken by all parties to insure that potentially harmful chemicals are not added inadvertently to our food supply. However, this pattern of Governmental regulation and concomitant industrial concern does not extend far beyond the perview of FDA, with growing exceptions in the areas of pesticides and consumer products.

With regard to the possible health and environmental risks associated with the thousands of other commercial chemicals not subject to regulations, neither government nor industry has exhibited adequate concern beyond the safety of plant workers from acute health effects. At the same time, during the past several years, industrial attention to new chemicals—reflected in substantial financial support of research and testing—seems to be increasing. Unfortunately, a similar level of concern over the non-acute affects of chemicals already in commerce is not apparent. For example, I suspect that current industrial support for chronic toxicity investigations of the fifty leading industrial chemicals is minimal—or perhaps imperceptible. Two reasons apparently underlie this benign neglect: (1) There are many producers of each chemical with no party clearly responsible for taking the lead in supporting safety investigations, and (2) An overconfidence exists that there are no problems due to the extensive experience with these chemicals without obvious adverse effects.

Turning to pollution control, much of the industrial effort to date has been reactive to federal, state, and local requirements which have usually been designed to reduce gross pollution effects. Clearly, progress is being made in controlling gross pollution, but at the same time far less attention is being devoted to the discharge of individual chemicals which could have delayed effects. In the near-term, only industry has the wherewithal to identify and abate the discharge of many of the particularly troublesome chemicals at individual plants. In the longer term, Government most likely will have to develop a similar capacity.

It is extremely important for a plant manager to know the chemical mix of the air emissions drifting over the plant fence into nearby neighborhoods. Similarly, he should be fully aware of the chemical cross section of his liquid and solid waste streams. This approach obviously means a serious physical monitoring effort on the part of industry—

monitoring not only for gross pollution but for individual chemicals as well. With rare exceptions such industrial monitoring programs do not currently exist.

Knowing what leaves the plant premises is of course only the first step. Determining the significance of such discharges—irrespective of the lack of Governmental requirements—is clearly the next step. Fortunately, many of the chemical pollutants that are frequently encountered have been studied rather extensively and assessing the effect of these chemicals on nearby neighborhoods should not be difficult. For the other chemicals which are not as well known accelerated industrial efforts to clarify their effects are mandatory.

I would hope that industry will take stronger initiatives in these areas rather than just waiting for Governmental regulations to descend. Strong, positive actions now by industry could very well temper eventual regulations that might otherwise be developed from a point of overreaction and cause unnecessary economic disruptions.

THE VINYL CHLORIDE CASE STUDY

During the past several months vinyl chloride has awakened all elements of the environmental community to the presence of the plastics industry. In some respects it is fortunate that we have been alerted in a rather dramatic fashion to the need for greater attention to this important segment of our industrial base which will surely continue to expand in the years ahead. Hopefully, we can extrapolate from our current experiences with VC and PVC in identifying problems with other potentially important commercial chemicals earlier in their embryonic stage and thus minimize the economic dislocations attendant to corrective actions.

To date EPA has exercised its authority in the pesticides area to suspend the use of vinyl chloride as a propellant in all pesticide products registered for indoor use in homes, food handling establishments, hospitals, and other enclosed areas, with a recall of stocks in the channels of trade. In addition, in response to the Agency's request, all registrants of pesticides which are used outdoors have agreed either to withdraw their registrations or to amend them to provide for the substitution of another propellant in their products.

We are currently investigating what regulatory actions, if any, are needed with regard to air emissions, water effluents, and solid waste disposal at facilities involved in VC and PVC activities. In addition the Agency has responsibility in the areas of drinking water standards, ocean disposal, and municipal waste disposal—all areas of some relevance to VC/PVC concerns.

EPA's initial concern in this area centered on reports in February of a materials loss of six percent in the PVC production process. Our detailed investigations indicate that these initial reports were in the correct range. Clearly, the percentage of losses will vary with the type of process, the age of the plant, the level of technology that is employed, and manufacturing practices. However, there is no doubt that in the United States substantial amounts of VC—probably exceeding 200 million pounds annually—and large quantities of PVC—probably exceeding 50 million pounds—are being discharged into the environment during the PVC production process. Most of the VC escapes directly into the atmosphere as air emissions, with lesser amounts dissolved in water effluent streams and entrapped in sludge and solid wastes. PVC losses occur as particulate in air emissions, suspended solids in water effluents, and components of solid wastes.

In considering non-worker populations, we are confronted with a host of new unanswered questions. How relevant to this concern are the data generated for estimating worker exposure risks? Can meaningful extrapolations be made from toxicological tests at relatively high dose levels to the lower levels of the dose-response relationship? Can realistic extrapolations be made from intermittent exposure, which characterizes the past and present toxicological and epidemiological investigations (e.g. eight hours per day, five days per week) to sustained exposure at the same dose levels or at lower levels? Are synergistic effects that result from exposure to other chemicals as well as VC influencing the worker's response to VC, and are there similar opportunities for such synergism within a non-worker population?

There are no sharp answers to these questions, and indeed they go to the heart of many of the fundamental uncertainties of the biological sciences. To date the epidemiological and toxicological data that have been generated have been directed almost exclusively to concerns over workers. This is the data base that we in EPA presently have available. I doubt that anyone is more aware of its inadequacy than are those of us responsible for regulatory actions based on this data. Unfortunately, we often have no choice but to make judgmental decisions using whatever scientific information is available.

We are obviously concerned about current and future background levels of VC in the air and in the water throughout the country. Our more immediate

efforts, however, are being directed to determining ambient and peak levels near chemical plants. Recently, we initiated a nationwide sampling and analysis program to determine, at least in a preliminary fashion, the VC levels in ambient air and in water and semi-solid effluents at thirteen PVC plants. These activities are currently underway, and we hope to have the results very soon.

There has been considerable discussion of the amount of unreacted VC monomer remaining in PVC and the rates of migration out of the PVC. Many companies are now seized with this problem, and I suspect the number of samples being taken to determine VC concentrations and migration rates has increased considerably in recent weeks. We do not know whether such migration from finished products contributes significantly to background levels of VC, but as you are aware FDA is seized with several aspects of this problem directly related to food. Should there be high levels of VC background in the environment, then our concern over all sources of VC—including migration from many products—should intensify.

TOXIC SUBSTANCES IN THE MID-1980's

By 1985, more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently suspected effects.

From the toxic substance point of view the quality of life in the chemical age of the Eighties, relative to the current quality of life, depends, in large measure, on the outcome of the competition between population and economic growth on the one hand and the sophistication in approaches to responsible regulation—by both industry and government. Clearly, more people will be exposed to more chemicals in more situations. Hopefully, we can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly toward toxic substances through its Governmental and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts. To avoid such a situation, the highest quality of government leadership in this area is essential—leadership characterized by technical credibility and openness in dealing with controversial data.

If the regulatory pattern of the Sixties and Seventies continues, during the Eighties the number of toxic substances other than chemicals associated with foods, drugs, cosmetics, and pesticides regulated by Government will be relatively few—in the dozens rather than hundreds or thousands. However, each of these regulatory decisions will be significant in that they will set the framework and the standards for the efforts of industry in self-regulation of the bulk of the industrial chemicals.

Industry will probably be using testing and related approaches to product safety which are not significantly different from current approaches. The Governmental thicket of regulations may inadvertently drive some of the smaller companies out of new product development. Concurrently, closer Governmental scrutiny of industry activities may be necessary in the face of potential legal problems as the larger companies consolidate their positions.

By 1985, most of the emission stacks and effluent pipes will be plugged. Our toxic substance concerns will center largely on contaminants, non-point sources, direct product exposure, and generally unattributable build-up of toxic chemicals in the environment. And, as the gross pollution effects subside, previously undetected effects of individual and combinations of chemicals in the water and in the air will probably be unmasked.

Risk/benefit approaches should be well accepted within a decade, although concerns will penetrate much more deeply into social as well as economic values. There should be far less concern over the concept of accepting different levels of risk for different chemicals, depending on their social utility. And at the same time the role of corporate responsibility should be better accepted by all concerned.

REGULATORY ASPECTS AND RESEARCH NEEDS

Conference on Public Health Implications
of Components of Plastics Manufacture
National Institute of Environmental
Health Sciences
Pinehurst, North Carolina
August 29, 1974

This Conference has underscored the many gaps in our understanding of the behavior of vinyl chloride and the inadequacies of current research efforts to improve the data base which supports the regulatory decisions that must be made now. In addition to the need for much better information on the human health effects of exposures to low levels of vinyl chloride, we know relatively little about

- the persistence of vinyl chloride in air and water and the degradation products associated with this chemical
- the ecological effects of vinyl chloride, particularly as it interacts with aquatic organisms
- the rates of migration of unreacted vinyl chloride monomer from products containing PVC during their use and disposal.

Perhaps, even more importantly the Conference has highlighted what many environmentalists are calling the "tip of the iceberg"—an iceberg of chemical problems that will continue to float to the surface during the decades ahead. For example, the array of hundreds of chemicals added to plastics that was shown here clearly illustrated the complexity of the task of the researcher in attempting to provide an early warning of future problems.

It certainly appears that except for continuing concern over spills and accidents, Government and industry have been rather complacent with regard to the potential environmental threat from the high volume industrial chemicals. This complacency is in large measure attributable to the relative absence of visible and uncontrolled dangers from exposure to the chemicals during their long histories. In addition, since many of these chemicals are manufactured by a number of companies, firms may lack incentive to invest individual company resources to clarify the safety aspects of their usage. Clearly, the experience with vinyl chloride—the twenty-second leading chemicals in terms of production—underscores the problems that can result from such complacency. Despite the continuing commercial importance of these high volume chemicals, it cannot be assumed that adequate research, testing, and related safety measures will be taken by industry, and vigorous governmental leadership in this area seems essential.

The most immediate task confronting us all is how to organize the limited resources—and I refer principally to dedicated scientific talent—of Government and industry to sort out the areas requiring the most urgent attention. Should the Toxic Substances Control Act be enacted, the Federal Government will have a new responsibility of particular importance to the prioritization of these efforts. Hopefully, such a legislative mandate can provide the impetus for more concerted efforts toward early recognition and correction of potentially serious chemical problems.

This Conference has been a useful first step toward imparting a sense of direction for addressing the many unknown aspects of the plastics industry. It certainly has helped clarify the dimensions of the problem. Clearly industry must play a key role—in monitoring, testing, and, where appropriate, restraint—for in many cases only the manufacturer of the chemical is in a position to suspect the likelihood of hidden hazards associated with his products.

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CHEMICALS AND THE ENVIRONMENT: THE FUTURE IS NOW

25th Constitutional Convention of the
International Chemical Workers Union
Las Vegas, Nevada
September 23, 1974

CHEMICALS, THE WORKER, AND THE ENVIRONMENT

It is indeed a privilege to be able to participate in this meeting at a time when chemicals are in the forefront of your concerns and of mine. These past twelve months have been punctuated with repeated warnings that Government, industry, and labor must direct greater attention and additional resources to clarifying the risks associated with chemicals. We cannot afford to learn about these risks after the damage is done, but at the same time we cannot act precipitously and unnecessarily curtail the influx of chemical products so essential to the viability of our economy.

Let me recount a few of the events of recent months as viewed from the perspective of the Environmental Protection Agency—events which clearly dispell any notion that our concerns are only hypothetical, and unfortunately document the reality of the problem.

— Last year the discovery of unusually high levels of asbestos in the drinking water of Duluth, Minnesota, gave impetus to a series of court actions and at the same time stimulated extensive Governmental efforts to clarify the hazards related to the inhalation or ingestion of asbestos.

— More than a dozen carcinogens that pose a potential hazard in the work place have been identified and strict precautionary measures prescribed. Of particular environmental concern is benzidine in view of its widespread distribution in dyes and fabrics.

— The imprint on the worker and the environment of vinyl chloride may be with us for many years to come. The problems we have uncovered in recent months in addressing vinyl chloride have raised a host of questions with regard to all of the high volume industrial chemicals.

— Last Friday, hearings were held in Washington on arsenic. An unusually high incidence of cancer among workers exposed to arsenic has been reported, and there have also been reports of high levels in the crops and in the population adjacent to at least one smelter.

You may ask why a representative of the Environmental Protection Agency—which has no authority within the plants—was asked to speak to this gathering which is concerned with the worker. As you know, the Department of Labor and not EPA has the primary Governmental responsibility for safety in the work place. Our responsibility begins at the fenceline. However, there are at least four reasons why EPA is concerned with the worker, and why I spend many hours in meetings with our colleagues from the Department of Labor.

— We are vitally concerned with the health and welfare of neighoorhoods adjacent to industrial complexes. More often than not a large proportion of the residents are workers and their families.

— Secondly, pollution control is not free, and the costs of compliance with EPA regulations can result in economic dislocations for the affected industries with the livelihood of the workers often at stake.

— In addition, many of the costs of pollution control are passed on to the consumer and I need not tell you who is the first to feel the impact of higher prices for consumer products.

— Finally, the Department of Labor and EPA regulate many of the same chemicals. Neither of us has enough resources to do an adequate job. Hopefully, by sharing our experiences we both will be able to do a better job.

20,000 CHEMICALS

About 20,000 chemical substances are commercially produced and used in the United States, with 500-700 new substances entering commerce annually. They find a wide variety of uses as industrial chemicals, in consumer products, and in specialized uses such as drugs, food additives, and pesticides. We estimate that about ten percent of U.S. industry is directly involved in introducing chemical changes into its products.

The problems presented by the presence in the environment of some chemical substances are all too well known. Others are believed to pose a latent health or environmental threat, while the effects associated with many of the remaining chemicals, acting individually or synergistically, are almost completely unknown. However, it seems clear that

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the problems associated with the presence of many chemical substances in the environment will undoubtedly continue to grow in number, severity, and complexity in the years ahead.

Some of the hazards associated with chemical substances have been recognized and are controlled by the Government, e.g. pesticides and drugs. Other aspects of the problem have only recently been identified, and appropriate regulatory measures do not yet exist. Still other pieces of the problem have yet to be identified. Many gaps remain in understanding why, how, and when a substance can have a negative impact on health or the environment, and how best to control or prevent such hazards.

Thus, our concern is two-fold: identification and assessment of the risks associated with the manufacture, distribution, use and disposal of chemicals which could adversely affect health and environmental quality; and practical steps, including regulatory actions as appropriate, to prevent or mitigate the problems posed by such chemicals. Paramount in these concerns must be the safety of the worker, who invariably has the greatest degree of exposure to the broadest range of chemicals.

VINYL CHLORIDE—BETTER LATE THAN NEVER?

In January 1974, the B.F. Goodrich Company, the largest U.S. producer of PVC resin, notified the National Institute of Occupational Safety and Health that four workers from its PVC, polymerization plant in Louisville, Kentucky, apparently had died from a rare cancer, angiosarcoma of the liver. All four workers had been closely associated for many years with the production of PVC resins. The rarity of the tumor and the clustering of deaths at a single plant raised suspicions that an occupational disease related to vinyl chloride exposure had been found. Since that time, ten additional cases of this tumor, which developed in U.S. PVC polymerizations workers since 1961, have been confirmed. This tumor has also been reported in seven workers at European polymerization plants, one worker at a U.S. PVC fabrication plant, two workers at European fabrication plants, one worker at a European vinyl chloride plant, and two residents in the general population near U.S. fabrication plants.

Concurrently, toxicological data from animal studies became available which further strengthened the suspicion of vinyl chloride as the etiological agent in the formation of the liver cancer. A broad spectrum of cancers was reported by Professor Cesare Maltoni of Italy in different animal species at various exposure levels. His inhalation studies of rats exposed to 50 ppm at repeated intervals approximating occupational exposures have produced angiosarcomas of the liver and abdomen as well as tumors of the kidney and skin. In mice exposed to vinyl chloride the same tumors have been observed, with the addition of lung tumors. Animal studies sponsored by U.S. industry have confirmed Maltoni's observations at 50 ppm. Recent epidemiological studies also suggest the possibility of multiple cancers attributable to exposure to vinyl chloride.

Meanwhile, statements by industry and Government officials indicated that the material loss to the environment during the PVC polymerization process may be about six percent, with more than 75 percent of the losses being vinyl chloride air emissions. Also, it soon came to light that vinyl chloride was being used as a propellant in aerosol sprays, and we were becoming more aware of railroad accidents involving vinyl chloride tank cars.

This series of events has finally stimulated a broad range of corrective actions by Government and industry—actions that should have been taken many years ago. The Governmental actions include:

- The banning of the use of vinyl chloride as a propellant in aerosol sprays by EPA, FDA, and the Consumer Product Safety Commission.
- Revision downward by the Department of Labor of the standard for allowable levels of vinyl chloride in the work place.
- Development by EPA of an air emission standard for vinyl chloride.
- Development by FDA of regulations limiting the amount of unreacted vinyl chloride monomer in food packaging containing PVC.
- Broad monitoring programs by EPA and other agencies to determine actual levels of vinyl chloride within plants, near chemical complexes, and in other areas.
- Expanded research to clarify further the health aspects of exposure to vinyl chloride and the behavior and fate of this chemical in the environment.

Many of you may be particularly concerned with the possibility of a vinyl chloride hazard associated with PVC fabrication activities. Initially, the Government's primary concern and investigative activities centered on the polymerization process. Only now, with the recent reports of angiosarcoma among former fabricators, has attention been directed to the more than 8,000 fabrication plants. The first step obviously is reliable monitoring—and I emphasize reliable—to determine existing levels. I regret to report that at present there is not available information which would enable us to provide any guidance on the likely hazard, if any, in or around fabrication plants.

Industry, of course, has a special responsibility concerning vinyl chloride. Let me outline some of these areas of responsibility as viewed from the EPA perspective.

Reducing Discharges of VC and Other Toxic Chemicals

There is no doubt that industry has taken and can continue to take a variety of immediate steps at relatively little cost to reduce vinyl chloride discharges. During the past few months many plants have already started to tighten maintenace and operating procedures; other plants are installing improved pumps, seals, and disconnect devices; while still other plants are introducing more significant process changes. One company is reportedly spending $3 million to tighten the processes at a single PVC facility; another company reports that it has 100 engineers working to introduce modifications that will dramatically cut vinyl chloride losses at several plants.

Medical Surveillance

Clearly, recent concerns have triggered extensive medical surveillance programs of workers throughout the industry. These programs should become routine to cover a far broader swath of chemicals and other chemical complexes. Published analyses of the results of such programs would be very valuable to Government agencies. In addition, industry should support medical surveillance programs for residents in neighborhoods adjacent to PVC complexes and other types of plants releasing chemicals into these neighborhoods. The character of such surveillance will obviously depend on the type of chemicals involved and the arrangements that can be worked out by industry with local health authorities.

Fenceline Monitoring for Chemical Discharges

Traditionally, the chemical industry has conducted very little fenceline monitoring not required by federal, state, or local agencies to determine the chemical discharges leaving plant property. Clearly, a plant manager should know the chemical mix of the air emissions drifting over the plant fence into nearby neighborhoods. Similarly, he should be fully aware of the chemical cross section of his liquid and solid waste streams. Thus, a far more intensive physical monitoring effort on the part of industry is needed.

Toxicological Testing

Until recently, the efforts of U.S. industry to clarify the chronic toxicity of vinyl chloride were nearly negligible, despite the commercial importance of this chemical. The studies to date have not been adequate, in terms of direction, scope, or quality. Even the additional toxicological studies which have been proposed calling for animal exposures down to 1 ppm may not be sufficient.

Testing for Persistence and Environmental Effects

A related area is industry's responsibility to clarify the environmental fate and effects of the chemicals it manufactures, and in this case the behavior of vinyl chloride in water and air (including degradation products) and the fate and effects of products containing PVC in soil and water. This is a new area which has not attracted sufficient attention from industry but which is of crucial importance in assessing environmental impacts of chemical activities. Governmental leadership will probably be essential in helping to point the way as to the types of tests and analyses that are the most appropriate.

Testing for Levels of Unreacted Monomer

In view of the likelihood that FDA will limit the levels of unreacted monomer allowed in PVC food packaging, industry has recently accelerated efforts to analyze the levels of vinyl chloride that are present in PVC resin used for food packaging and in the packaging itself. This relatively inexpensive procedure should be extended to other types of products as well. It is particularly important that the manufacturers of resin, who in general are well equipped to carry out the necessary sampling and analysis, advise their customers (i.e., the fabricators).

of the quality of the resin in terms of unreacted monomer in addition to the usual quality criteria. The fabricators in turn have a responsibility to be aware of the levels of unreacted monomer that persist in the products that eventually reach the marketplace.

THE NEED FOR A LEGISLATIVE MANDATE

The fate of the much needed Toxic Substances Control Act will be decided in Washington during the next few days—a decision that can have a direct and profound impact on our society in general, and the worker in particular. For three years this legislation has been delayed in the Congress. Despite the broad consensus that the legislation is clearly needed, procedural delays and delays over details have prevented prompt action by the Congress.

I know of no group with a more vital stake in this legislation than this audience. What more dramatic evidence than the vinyl chloride case is needed to underscore the urgency of greater Governmental and industrial responsibility in this area?

The Toxic Substances Control Act would provide new authority for (a) information acquisition, and (b) restrictive actions. The Government could require industrial testing of chemical substances (both existing and new) which are suspected to pose unreasonable risks and also require other information from manufacturers produced, actual or intended uses, and known by-products. Then, if warranted, the use and distribution of chemical substances found to pose unreasonable risks could be restricted.

This new authority is important from two standpoints. First, the Federal Government is given direct authority to restrict substances presently in commercial use that are known to cause health or environmental hazards, and when effects information is lacking, to require testing of the substance by the manufacturer to assess human or environmental impact. Second, for substances not yet in commercial production, premarket testing and review of chemicals suspected to be hazardous could be required. Thus, there would be the opportunity to assess the risks before the new substances are commercially produced and to take appropriate regulatory action to prevent toxic incidents.

The authority to require industrial testing of chemicals is designed to support the needs of both EPA and the Department of Labor. However, the new authority to regulate chemicals is limited to chemicals outside the work place since there is no intention to undercut the existing authority of the Department of Labor in any way.

LOOKING AHEAD

In decades ahead, more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically are much farther reaching than currently suspected effects.

In a few years the emission stacks and effluent pipes will be largely plugged, and hopefully sensible land disposal of hazardous wastes will be required. At the same time, however, more people will be exposed to more chemicals in more situations—exposure from contaminants, non-point sources, direct product contact, and generally unattributable buildup of chemicals in the environment. The chemical worker will continue to be on the front line of much of the exposure. I am confident that society can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly in anticipating and remedying toxic chemical problems through its Governmental and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts—which would be tragedy for us all.

With increasing frequency we are being awakened to the latent health hazard from chemicals that have not been adequately tested or analyzed. We are becoming more and more concerned not only with the problems that emerge today but with those that will only be recognized tomorrow. Preventive actions are the key; corrective actions can only be inadequate and disruptive.

We have met the future, and it is now.

VINYL CHLORIDE: THE TIP OF THE ICEBERG?

Conference on VCM - The Processor's Perspective
Society of Plastics Engineers, Inc.
Palisades Section ★ Vinyl Plastics Division
New York, New York
October 31, 1974

CHEMICALS, INDUSTRY, AND THE ENVIRONMENT

About 20,000 chemical substances are commercially produced and used in the United States, with 500-700 new substances entering commerce annually. They find a wide variety of uses as industrial chemicals, in consumer products, and in specialized uses such as drugs, food additives, and pesticides. We estimate that about ten percent of U.S. industry is directly involved in introducing chemical changes into its products.

The problems resulting from the presence in the environment of some chemical substances are all too well known. Others are believed to pose a latent health or environmental threat, while the effects associated with many of the remaining chemicals, acting individually or synergistically, are almost completely unknown. However, it seems clear that the problems associated with the presence of many chemical substances in the environment will undoubtedly continue to grow in number, severity, and complexity in the years ahead.

Some of the hazards associated with chemical substances have been recognized and are controlled by the Government, e.g. pesticides and drugs. Other aspects of the problem have only recently been identified, and appropriate regulatory measures do not yet exist. Still other pieces of the problem have yet to be identified. Many gaps remain in understanding why, how, and when a substance can have a negative impact on health or the environment, and how best to control or prevent such hazards.

Thus, our concern is two-fold: Identification and assessment of the risks associated with the manufacture, distribution, use, and disposal of chemicals which could adversely affect health and environmental quality; and practical steps, including regulatory actions as appropriate, to prevent or mitigate the problems posed by such chemicals. In addressing these concerns we must, of course, maintain an appreciation of the role of these chemicals in our economy and of the societal benefits that chemicals have brought to all of us.

THE CASE OF VINYL CHLORIDE: BETTER LATE THAN NEVER?

The Emergence of the Problem

In January 1974, the B. F. Goodrich Company, the largest U.S. producer of PVC resin, notified the National Institute of Occupational Safety and Health that four workers from its PVC polymerization plant in Louisville, Kentucky, apparently had died from a rare cancer, angiosarcoma of the liver. All four workers had been closely associated for many years with the production of PVC resins. The rarity of the tumor and the clustering of deaths at a single plant raised suspicions that an occupational disease related to vinyl chloride exposure had been found. Since that time, at least 10 additional cases of this tumor, which developed in U.S. PVC polymerization workers since 1961, have been confirmed. This tumor has also been reported in a number of workers at European polymerization and monomer plants, one worker at a U.S. PVC fabrication plant, two workers at European fabrication plants, and two residents in the general population near U.S. fabrication plants.

Concurrently, toxicological data from animal studies became available which further strengthened the suspicion of vinyl chloride as the etiological agent in the formation of the liver cancer. A broad spectrum of cancers was reported by Professor Cesare Maltoni of Italy in different animal species at various exposure levels. His inhalation studies of rats exposed to 50 ppm at repeated intervals approximating occupational exposures have produced angiosarcomas of the liver and abdomen as well as tumors of the kidney and skin. In mice exposed to vinyl chloride the same tumors have been observed, with the addition of lung tumors. Animal studies sponsored by U.S. industry have confirmed Maltoni's observations at 50 ppm. Recent epidemiological studies also suggest the possibility of multiple cancers attributable to exposure to vinyl chloride.

Meanwhile, statements by industry and Government officials indicated that the material loss to the environment during the PVC polymerization process may be about six percent, with more than 75 percent of the losses being vinyl chloride air emissions. Also, it soon came to light that vinyl chloride was being used as a propellant in aerosol sprays, and we were becoming more aware of railroad accidents involving vinyl chloride tank cars.

This series of events finally stimulated a broad range of corrective actions by Government and industry—actions that should have been taken many years ago. Given the long history of PVC production which in the past resulted in much higher levels of exposure to workers and to the general population than are encountered today—together with the long latency period between exposure and the development of angiosarcoma—we obviously are very concerned that many of the consequences of the somewhat reckless handling of vinyl chloride in the past will continue to be uncovered for some years to come.

The Fabrication Process

Many of you may be particularly concerned with the possibility of a vinyl chloride hazard associated with PVC fabrication activities. Initially, the Government's primary concern and investigative activities centered on the polymerization process. Only very recently, with the reports of angiosarcoma among former fabricators, has attention been directed to the more than 8,000 fabrication plants. A first step obviously is reliable monitoring—and I emphasize reliable—to determine existing levels. I regret to report that at present we do not have good information which would enable us to provide guidance on the likely hazard, if any, in or around fabrication plants. Since the only source of vinyl chloride at most of these plants is the unreacted monomer that may be present in the PVC resin, we would not expect the air emissions to be high. At the same time, however, these facilities are often in metropolitan areas which could result in exposure to very large numbers of people.

At the outset the major concerns of the Environmental Protection Agency with regard to fabrication activities related to other chemicals. For example, information is not readily available indicating whether any substantial risk might be involved from the ingestion or inhalation of PVC particulate. Also, a large number of chemicals are used in PVC products as antioxidants, antistatics, colorants, fillers, plasticizers, and stabilizers, and many of them can reach man through a variety of routes. The health effects of some of these chemicals are reasonably well known; the effects of others have yet to be explored. Several of them are particularly good candidates for more detailed investigations, e.g. cadmium, barium.

Disposal of Products Containing PVC

Hydrogen chloride is the major toxic material released when PVC is burned. On the order of 32,000 tons of PVC are burned annually, releasing approximately 18,500 tons per year of HCl as air emissions. At the same time much more HCl is probably now emitted to the atmosphere from coal-burning power plants than from municipal incinerators. However, there still could be a hazard in the immediate vicinity of an incinerator as a direct result of its HCl emissions.

HCl can also be major factor related to corrosion during incineration at certain temperatures. Specifically, incinerators with heat exchangers will have corrosion problems on the fire side of the exchange equipment when the combustion gases contact the outer metal surface. Also, about 95 percent of our incinerators have some type of air pollution control equipment that is exposed to the high chloride environment resulting from refuse combustion. The cooling and precipitating water from the scrubbers that contacts the flue gas contains large quantities of chloride and is extremely corrosive to the structure.

It is highly unlikely that large quantities of vinyl chloride will be emitted during incineration of PVC. There is no evidence that PVC will chemically revert to vinyl chloride. Some small amounts of entrapped monomer might conceivably survive incineration, but these quantities would be very low.

Other air, water, or soil contaminants could result during disposal of PVC products. The types of additives of particular concern are: antioxidants—phenols, amines, phosphates, and sulfur compounds; antistatics—amine derivatives, quaternary ammonium salts, phosphate esters, polyethylene glycolesters; colorants—salts or oxides of metals, aluminum, copper, and inorganic pigments; fillers—silica, glass, calcium carbonate, metallic oxides, carbon, cellulose fillers, asbestos; plasticizers—phthalates, organic phosphates; stabilizers—lead salts of acids, barium, cadmium, calcium, zinc, alkyl tin compounds.

Recommendations of the EPA Task Force

Last month the EPA Vinyl Chloride Task Force, which had been established in February, submitted its Report to the Administrator. This Report included the results of our initial monitoring

program at ten PVC resin and two monomer plants, preliminary analyses of the health effects of vinyl chloride, studies on the fate and environmental effects of vinyl chloride, and investigations of industrial practices. Upon receipt of the Report, Mr. Train announced that he had accepted the recommendation for the Agency to establish an air pollution emission standard for monomer and PVC resin plants and concurrently to investigate further the need for a standard applicable to fabrication plants. The eighteen other recommendations for Agency action are currently in various stages of implementation.

The process of setting an air emission standard under the Clean Air Act will involve several months of additional monitoring and other investigations, data collection, public hearings, and other regulatory steps as required by the Act. An environmental impact statement will be prepared, and public hearings held, to insure full public participation in the development of this standard. The current timetable is to promulgate the standard within about one year.

Initial estimates indicate that using available control technology emissions could be reduced by about 75 percent from PVC resin plants and 90 percent from monomer plants, with a concomitant cumulative increase in the cost of PVC resin of about four percent. Also, it is estimated that the available control technology, which includes a variety of control measures applicable to the multiple emission points within the plants, could be in place from within several months to two years after promulgation of appropriate regulations.

With regard to fabrication plants, monitoring of the vinyl chloride levels in the ambient air near five plants is planned as an early step to determining the need for an air emission standard.

I do not plan to list the other recommendations set forth in the Task Force Report. However, recent activities directed to carrying out several of the recommendations may be of interest.

Studies are currently in progress to determine the amount of vinyl chloride migrating out of PVC products used in water distribution systems, such as PVC pipe or storage tank liners. In laboratory experiments, 3/4 inch PVC pipe simulating household installations is being used. Also, water samples from a reservoir that had recently installed a new PVC liner are being analyzed.

Another area of immediate concern relates to additional research on the environmental fate and effects of vinyl chloride. We believe that industry has a major responsibility to carry out such research; however, in view of the newness of this area EPA is conducting limited investigations that will help point the way as to the most appropriate types of studies. Our research laboratory in Duluth, Minnesota, has begun acute bioassay studies and will soon initiate limited chronic bioassay tests on selected aquatic species. Meanwhile, our laboratory in Athens, Georgia, will expand its previous work on the aquatic fate of vinyl chloride with experiments on the uptake and degradation by microorganisms, chemical and photochemical transformation, and air-water exchange. Finally, research at our laboratory at Research Triangle Park, North Carolina, centers on photochemical degradation products of vinyl chloride.

Another recommendation called for studies near disposal sites of waste products from PVC plants and or municipal waste to determine if toxic substances are leaching into the soil or ground waters. The first study will soon begin.

INDUSTRY'S RESPONSIBILITY

Reducing Discharges of Vinyl Chloride and Other Toxic Chemicals

There is no doubt that industry has taken and can continue to take a variety of immediate steps at relatively little cost to reduce vinyl chloride discharges. During the past few months many plants have already started to tighten maintenance and operating procedures; other plants are installing improved pumps, seals, and disconnect devices; while still other plants are introducing more significant process changes. One company is reportedly spending $3 million to tighten the processes at a single PVC facility; another company reports that it has 100 engineers working to introduce modifications that will dramatically cut vinyl chloride losses at several plants.

Medical Surveillance

Clearly, recent concerns have triggered extensive medical surveillance programs of workers throughout the industry; these programs should become routine to cover a far broader swath of chemicals and other chemical complexes. Published analyses of the results of such programs would be very valuable to Government agencies.

Fenceline Monitoring for Chemical Discharges

Traditionally, the chemical industry has conducted very little fenceline monitoring not required by federal, state, or local agencies to

determine the chemical discharges leaving plant property. Clearly, a plant manager should know the chemical mix of the air emissions drifting over the plant fence into nearby neighborhoods. Similarly, he should be fully aware of the chemical cross section of his liquid and solid waste streams. Thus, a far more intensive physical monitoring effort on the part of industry is needed.

Toxicological Testing

Until recently, the efforts of U.S. industry to clarify the chronic toxicity of vinyl chloride were nearly negligible, despite the commercial importance of this chemical. The studies to date have not been adequate, in terms of direction, scope, or quality. Even the additional toxicological studies which have been proposed calling for animal exposures down to 1 ppm may not be sufficient.

Testing for Persistence and Environmental Effects

A related area is industry's responsibility to clarify the environmental fate and effects of the chemicals it manufactures, and in this case the behavior of vinyl chloride in water and air (including degradation products) and the fate and effects of products containing PVC in soil and water. The research by EPA should help structure such tests, but the primary responsibility rests with industry.

Testing for Levels of Unreacted Monomer

In view of the likelihood that FDA will limit the levels of unreacted monomer allowed in PVC food packaging, industry has recently accelerated efforts to analyze the levels of vinyl chloride that are present in PVC resin used for food packaging and in the packaging itself. This procedure should be extended to other types of products as well. It is particularly important that the manufacturers of resin, who in general are well equipped to carry out the necessary sampling and analysis, advise their customers (i.e., the fabricators) of the quality of the resin in terms of unreacted monomer in addition to the usual quality criteria. The fabricators in turn have a responsibility to be aware of the levels of unreacted monomer that persist in the products that eventually reach the marketplace.

LESSONS LEARNED FROM THE VINYL CHLORIDE EXPERIENCE

Many environmentalists are convinced that the problems of vinyl chloride are but the tip of a chemical iceberg—an iceberg of problems that will continue to float to the surface during the decades ahead.

It certainly appears that except for continuing concern over spills and accidents, Government and industry have been rather complacent with regard to the potential environmental threat from the high volume industrial chemicals. This complacency is in large measure attributable to the relative absence of visible and uncontrolled dangers from exposure to the chemicals during their long histories. In addition, since each of these chemicals is manufactured by a number of companies, firms may lack incentive to invest individual company resources to clarify the safety aspects of their usage. Clearly, the experience with vinyl chloride—the twenty-second leading chemical in terms of production—underscores the problems that can result from such complacency. Despite the continuing commercial importance of these high volume chemicals, it cannot be assumed that adequate research, testing, and related safety measures will be taken by industry, and vigorous governmental leadership in this area seems essential.

The experience with vinyl chloride has triggered a series of actions within the Federal Government directed to a broader range of chemicals of considerable interest to the plastics industry. Let me touch on just three of these activities:

— Interagency efforts in Washington to identify problem chemicals used in the plastics industry have expanded considerably in recent months. Beginning with a meeting at Pinehurst, North Carolina, in August, there have been a number of interagency consultations and discussions concerning various aspects of the plastics industry. I do not know what actions, if any, will result from this upsurge of interest.

— In accordance with one of the Task Force recommendations, EPA is currently reviewing governmental regulatory and research activities directed to high volume industrial chemicals in general. A number of these

chemicals are clearly of interest to the plastics industry. Again no specific actions are being contemplated at this time.

— The World Health Organization has recently entered the plastics arena. During a meeting earlier this month considerable attention was given to the health and environmental aspects of plasticizers and flame retardants used in plastics and in textiles.

Also, as most of you know, the fate of the much needed Toxic Substances Control Act, which has been delayed in the Congress for three years, will be decided during the next few weeks. This legislation can provide the basis for more concerted efforts by Government and industry to assess the problems of toxic chemicals and to take corrective steps, when needed. The aim is to take these steps early in the life of a chemical, thus minimizing health and environmental risks, and also reducing the attendant economic dislocations.

LOOKING AHEAD

In the decades ahead, more chemicals will be in commerce, the properties of many chemicals will be better understood, and consequently the list of chemicals considered to be hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently suspected effects.

In a few years the emission stacks and effluent pipes will be largely plugged, and hopefully sensible land disposal of hazardous wastes will be required. At the same time, however, more people will be exposed to more chemicals in more situations—exposure from contaminants, non-point sources, direct product contact, and generally unattributable buildup of chemicals in the environment. I am confident that society can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly in anticipating and remedying toxic chemical problems through its governmental and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts—which would be a tragedy for us all.

The iceberg is emerging.

With increasing frequency we are being awakened to the latent health hazard from chemicals that have not been adequately tested or analyzed. We are becoming more and more concerned not only with the problems of today but with those that will only be recognized tomorrow. Preventive actions are the key; corrective actions can only be inadequate and disruptive.

We have met the future, and it is now.

THE TECHNICAL IMPLICATIONS OF TOXIC SUBSTANCES LEGISLATION

Symposium on Toxic Substances Control
and OSHA/NIOSH Regulations
Synthetic Organic Chemical
Manufacturers Association
Washington, DC
January 29, 1975

LIMITED PROGRESS IN 1974

To many persons interested in more effective approaches to the control of toxic substances, 1974 may have seemed like a very eventful year. OSHA, FDA, and EPA were all very active on the regulatory front; and the judiciary became more involved than ever before—addressing asbestos, mercury, dieldrin, vinyl chloride, and a number of other chemicals.

However, in many ways 1974 was a disappointing year even while the tip of the iceberg of toxic substances problems continued to break through the surface of environmental damage on a broad front. From my perspective relatively little progress was made toward developing a more systematic approach for addressing the sources of toxic substances problems that are appearing with increasing frequency in the general environment. Significant additional resources were not forthcoming from either Government or industry for more concerted efforts directed to identifying chemical problems early and to taking preventive actions before major commercial investments are in place. And the legislative basis for corrective action remains fragmented and uncertain.

Perhaps the most significant development during 1974 was the enactment of legislation designed to insure the safety of our drinking water supplies. This wide array of new authorities will undoubtedly have a major impact on many facets of our society in the months and years ahead. As the implementation of this new legislation unfolds, we will become increasingly aware of the multi-media character of many of the chemical problems we have tended to view in a narrow perspective.

CHEMICAL PROBLEMS CONTINUE TO EMERGE

During 1974 an array of old and new chemical contaminants emerged as recognizable near-term health hazards. Indeed, many of us have now become so pre-occupied with health hazards that we frequently tend to neglect the adverse ecological effects from toxic chemicals. Summarized below are a few of the recent chemical concerns that prompt meetings such as this one.

- Vinyl chloride certainly has focused the attention of the entire environmental and industrial communities on the need for more careful attention to the high volume industrial chemicals in general, and plastics in particular. The emergence of polyvinyl chloride as an environmental concern has underscored the presence of previously unsuspected problems associated with air emissions at manufacturing facilities. Also, new concerns have been raised over unreacted monomer contamination of polymers and the leaching into the environment of toxic additives in plastics during use of disposal of plastic products.
- Trace amounts of a wide variety of halogenated organic compounds have been discovered in the New Orleans drinking water supply, including compounds strongly suspected of inducing serious chronic effects. These discoveries have raised questions about the possible problems resulting from the chlorination of waters containing chemical wastes which react with chlorine.
- Arsenic, which is present in many important natural ores and is also widely used in pesticides, has now been more strongly implicated as a possible etiological agent in cancer deaths among workers.
- Release of freon into the atmosphere has been cited by some experts as causing decomposition of the ozone layer. These experts fear that such depletion could lead to an increase in human exposure to ultraviolet light and thereby cause an increase in skin cancer.
- Health effects data on sulfuric acid mist, which has been identified as an indirect by-product from catalytic converters, point to the need for more caution in this area. More recently, with the advent of the energy crisis, concerns have also heightened that conversion of power plants from oil and gas to coal could further aggrevate the problem of sulfates in the air.
- Discovery of lead in the blood of children living near at least one copper smelter raises still another set of problems with regard to this well known toxic material.

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— Careful scrutiny of previously registered pesticides has identified a number of chemical compounds that in view of available substitutes seem to pose unnecessary health and environmental risks.

CONCEPTS EMBODIED IN THE PROPOSED TOXIC SUBSTANCES CONTROL ACT

A primary objective of this Conference is to discuss the shape and impact of toxic substances control legislation. Unfortunately, we are still some distance from knowing the intent of Congress in this area, and to comment on the details of an uncertain legislative framework seems a little presumptuous. Nevertheless, we have given considerable thought to the "implementability" of different types of legislative provisions and a few general comments may be helpful. My comments will be directed primarily to several of the concepts articulated in the *Conference Committee Working Print* that was prepared late last year, recognizing that the legislation that eventually emerges may be significantly different. Another caveat is that I do not intend to be thorough in this presentation but rather I will simply mention some of the highlights of our concerns.

Reporting Provisions

Three intertwined ideas are incorporated into the *Working Print* provisions calling for industrial reporting on the manufacture, use, and by-products of commercial chemicals, namely:

(1) An initial inventory report by industry on all commercial chemicals to provide a current production baseline. This inventory could then be used in determining future trends and in identifying new chemicals and new uses, as well as providing information on current activities as specific problems arise. Presumably this report inventory would be updated periodically—perhaps every five years. The intent apparently is to include all chemicals, including those produced even in the smallest quantities, in the inventory. Obviously, we are concerned as to how complete this inventory must be to serve its purpose, without unnecessarily taxing the resources of Government and industry in preparing and processing reports. In this regard, EPA would have authority to exempt manufacturers on a selective basis from reporting if the Agency finds that such reports are not needed. The House version of the *Working Print* would also exempt small business from this requirement.

(2) Annual reports to provide continuing information on selected chemicals of particular concern. These reports would assist in determining the need for, character of, and impact resulting from specific regulatory steps. Such judgments presumably would call for aggregated data, and particularly trend data, extracted from individual reports.

(3) Reports on new chemicals. All chemicals except those included in the original inventory list or explicitly exempted by the Administrator from the inventory would be considered to be new. EPA would presumably have the responsibility of publishing the names of the chemicals in the baseline inventory. A principal purpose of the reporting on new chemicals would be to insure the currency of the inventory.

The extent to which the foregoing reports would be used depends on (a) the Governmental resources made available to review and analyze the reports, and (b) the availability of the reports to organizations in addition to EPA, which in turn is heavily dependent on the amount of confidential information included in the reports and the procedures developed for handling confidential information.

I assume that the mechanics of the reporting system would derive from an appropriate regulation or set of regulations clarifying some of the uncertainties in terms such as "mixture" and "manufacturer", setting up a reporting schedule, and prescribing a report format. Presumably a standardized Governmental reporting form would further clarify how various uses and by-products are to be listed along with the appropriate identification of the chemical. The information would be presented in such a way as to facilitate its entry into an EPA data system, designed specifically to handle the reported information, with particular concern for the handling of confidential information.

Test Protocols

The general intent of the test protocol section of the *Working Print* seems reasonably straight forward, at least with regard to existing chemicals. A number of aspects will probably remain to be elaborated in regulations, such as the specificity of testing

requirements, perhaps more refined criteria for determining the need for testing, and identification of the responsible organizations to carry out testing for specific chemicals. If legislation is enacted, some additional guidance may be provided in all of these areas although many of the important decisions will undoubtedly have to be made on a case-by-case basis. It seems clear that test results must be standardized to the point that they provide an acceptable basis for Governmental decisions but not so standardized that sound and innovative industrial approaches to testing are inhibited.

In my view two of our concerns related to test requirements are particularly important. Testing should be required only in those cases when existing test data which are publicly available are not sufficient for making judgments concerning environmental or health risks. Secondly, to the extent possible test requirements under toxic substances legislation should be consistent with test requirements under other regulatory authorities directed to the same chemical classes. In this regard, we consider as very important the Pesticides Registration Guidelines currently under development by EPA.

During the past several years some companies have taken major steps to upgrade their testing activities—both in scope of coverage and in quality of personnel. I hope that with or without new legislation this trend will continue and extend to still broader segments of industry.

Premarket Screening

The concept of a list of selected chemicals and chemical classes would delimit the number of chemicals or chemical classes which could be subject to premarket screening requirements, either for (a) reviewing prior to introduction of new chemicals into commerce certain types of test data for the chemicals, or (b) reviewing in advance proposed new uses of existing chemicals. Thus, it seems that the list concept is directed principally to (a) newly developed chemicals which fall into particulary worrisome chemical classes that should be subjected to premarket test requirements, and (b) those existing chemicals which are of such concern that any significant new use should be carefully scrutinized in advance.

The area of premarket screening will undoubtedly receive additional attention as the legislation is further developed. If the list concept is adopted, there will certainly be additional debate concerning criteria for placing chemicals on the list. However, I suspect that the version that finally emerges will continue to be somewhat complicated both in concept and in detail.

Two additional aspects of importance related to premarket screening should also be noted. First, there may be a requirement for notices in the Federal Register of Governmental receipt of industrial reports submitted pursuant to premarket screening requirements. The concept is to provide an opportunity for public interest and other groups to evaluate data before a chemical enters the market or is subjected to a new use. Given industrial concerns over the confidentiality aspects of R&D activities, procedures must be worked out to insure that this industrial concern is given proper weight while at the same time the legislative requirement for publication of premarket information is met. A second area of interest relates to defining "uses". At present perhaps the best available means for defining uses would be a modified version of the Standard Industrial Code. Hopefully, in the longer run a better environmentally oriented scheme can be devised; however, development of an alternative workable system seems to be a very complicated task.

Regulating Hazardous Chemicals

The *Working Print* provides EPA with authority to regulate selected chemicals of particular concern, but presents only general guidelines concerning the criteria to be used in determining when limitations on chemical activities are appropriate. I am sure that you share our concern about the more detailed ground rules beyond broad legislative criteria that are used in assessing the need for limitations on toxic substances under this authority and other authorities as well. It seems important that to the extent possible, these ground rules be understood in advance by all interested parties, and indeed that all parties have a voice in shaping the ground rules.

As a step in this direction we have asked the National Academy of Sciences to extend its past studies of the approaches in assessing risks associated with toxic chemicals in order to help (a) clarify the best approaches to assessing benefits gained from society's use of chemicals and (b) develop techniques for balancing risks and benefits in the decision-making process. The Academy is now developing case studies of selected substances whose uses have been curtailed in the past by Government or industry, including DDT, polychlorinated biphenyls, and polybrominated biphenyls, as one input in determining how we can improve our

decision-making process. In several weeks a one-week working session involving representatives of Government, industry, labor, and public interest groups will be held by the Academy to develop specific recommendations concerning decision-making directed to toxic chemicals.

PROSPECTS FOR 1975

There seems to be little question that the number of problem chemicals of immediate concern will continue to grow during this year. More careful scrutiny by the plastics industry of its products will continue to identify particularly worrisome compounds, with polybrominated biphenyls, vinylidene chloride, acrylonitrile, and styrene already under investigation. The testing programs at the National Cancer Institute and other Government facilities will continue to identify important industrial chemicals, such as ethylene dibromide, which cause tumors in animals. As our monitoring efforts continue to expand, and particularly with the new thrust directed to drinking water, additional chemicals of concern will surely be identified throughout the country. In additional new problems will develop in unlikely places.

OSHA, FDA, and EPA will continue to take a variety of actions under existing regulatory authorities. All of these agencies are becoming increasingly sensitive to the important linkages among many of the regulatory standards in food and in the workplace and standards for the same chemicals in the general environment. We need to increase our efforts to improve the multi-agency approach to toxic substances problems.

With regard to EPA activities I am hopeful that faster progress can be made in the development of sound toxic effluent standards and refinement of Effluent Guidelines under the Federal Water Pollution Control Act. Our review of pesticides will continue to identify active and inert ingredients that require more stringent control. Meanwhile, the preparation and promulgation of pesticides regulations and guidelines will have a direct impact on the approaches of industry to toxicological testing. And, of course, further development of new source performance standards under the Clean Air Act will continue. These are but a few examples of EPA efforts which will continue to impact on the synthetic organics industry.

I am far less certain of legislative action during this new session of Congress. For four years there has been debate on the character of a Toxic Substances Control Act. I believe that there has been adequate debate, and now is the time for decisive action. Surely, the Congress will also be reviewing other regulatory authorities, as well, with a particular eye to the interaction of economic, energy, and environmental considerations.

CHEMICALS, REGULATIONS, AND THE ENVIRONMENT

Annual Meeting of the Soap and Detergent Association
Boca Raton, Florida
January 30, 1975

TOXIC CHEMICALS AND THE SOAP AND DETERGENT INDUSTRY

Extrapolation of effects from animals to man. Carcinogens, teratogens, and mutagens. Persistence, bioaccumulation, and degradation products. Rule making, hearings, and judiciatory processes. Action levels, tolerances, and interim standards. This jargon, characterizing the toxic substances trade, is rapidly becoming almost second nature to many of our industries through long and continuing involvement in the regulatory processes of Government. I suspect that there are few twists or turns in the regulatory obstacle course in Washington that a number of your companies have not encountered many times over.

To many of you the appearance of an EPA speaker on your program probably signals another revival of Governmental interest in phosphates or NTA. However, now that I have covered those topics, my further comments will be directed to somewhat broader aspects of our toxic substances concerns.

There is no doubt that in the years ahead your industry will be deeply immersed in coping with the ever expanding regulatory activities shaped by Congress and State legislatures, and carried out by Federal, State, and local agencies. Given the uses and eventual disposal of your products—in the household, by commercial service organizations, and by many sectors of industry—there will continue to be many opportunities for widespread exposure of man and the environment to the chemicals which you produce. The general concern over both the known and the unknown effects of these chemicals and over the interaction of these chemicals with other materials in the environment points to continuing scrutiny of your activities by Government, environmentalists, and the general public. Indeed, the public expects a greater degree of safety and environmental consciousness from your industry than from many other manufacturers of industrial and commercial chemicals.

I am hopeful that the soap and detergent industry will, in many respects, stay ahead of the often cumbersome Governmental machinery designed to protect our environment. By developing its own programs of responsible limitations on the use of toxic chemicals, industry frequently can reduce the need for overly extensive Governmental intervention into commercial activities which too often is painful for all concerned.

A GENERAL PERSPECTIVE

Direction of our Environmental Concerns

In his Environmental Message of December 1974, the President underscored the "maturity" of our enviromental commitment—a maturity that is critical to responsible integration of our economic, energy, and environmental objectives. This maturity must be reflected in the restraint shown by industry when considering the desirability of developing and using products which may have questionable health or environmental impacts. Similarly, environmentalists must exhibit moderation in the long overdue efforts to enhance the quality of the environment, efforts which frequently curtail commercial activities that are important contributors to economic growth.

With specific regard to the development and manufacture of chemicals, it is essential to adopt the President's call to reject the extremes and to accept the need for balancing environmental, economic, and energy concerns. Almost 15 percent of our industrial base is involved in introducing chemical changes into its products; a significant share of our energy resources is used as feed stock and as a source of power for this segment of industry; while at the same time many of the products and by-products of the chemical industry are discharged into the environment.

For many years, the primary emphasis of our environmental efforts has been to control what might be called gross pollution effects, including chemical oxygen demand, biological oxygen demand, and suspended solids in water effluents and SO_x, NO_x, and particulate in air emissions. While these efforts are of course continuing, there is now rapidly increasing attention being given to a number of toxic chemicals. This is not surprising in view of the growing list of recent environmental problems that have arisen throughout the country as the result of the presence of toxic chemicals, such as mercury, polychlorinated biphenyls, asbestos, arsenic, vinyl chloride, and more recently, organo-halogens in drinking water supplies.

Industrial Efforts to Reduce Environmental Problems

In recent years, many segments of industry have made very significant investments to control the discharge of effluents and emissions into the environment. These steps have been taken in large measure in response to Governmental requirements at the Federal, State, and local levels. There seems to be little doubt that such actions have had a dramatic effect in slowing the rate of degradation of our environment. However, all will agree that we still have a long way to go in cleaning up our air and water and in preserving our landscape.

Similarly, industry has over the years expanded its efforts to insure the safety of its chemical products—safety as viewed from the perspective of the worker, of the housewife, and of the general population. Such efforts have been spurred to a great extent by Governmental regulations, in some cases by the latent threat of lawsuits, and at times simply by good business practices. For many years, direct acute effects of chemicals have, of course, been of major concern; and more recently, complementary efforts have been directed to the longer term and more subtle health and ecological effects.

In some cases, industry has gone far beyond the requirements laid down by Government for pollution control levels to be achieved and for safety requirements. For example, one major chemical company has adopted the near term goal that all new plants be designed to achieve zero discharge with regard to process liquid waste effluents. Some companies have significantly expanded their staffs of toxicologists to address health problems beyond those of immediate interest in Government regulations. Other companies are conducting ecological effects tests on chemicals which by regulation are only required to be tested for their health effects. However, our general impression is that most companies are not moving much faster on the environmental front than the rate at which they are required by legally enforceable regulations.

Regulatory Framework

There are several regulatory authorities designed to limit the entry into the environment of toxic chemicals. For example, in the Clean Air Act and the Federal Water Pollution Control Act there are specific provisions directed to toxic and hazardous contaminants, and the pesticides laws are designed to prevent unnecessary environmental contamination from pesticides. While the laws administered by FDA, CPSC, and OSHA are not intended to protect the general environment, they do, of course, have some impact in this regard.

These and other regulatory authorities have required an ever increasing R&D commitment by industry. This trend will surely continue. I need not describe for you the impact of such requirements on the competitive positions of large and small companies, on the willingness of companies to risk investment in new products and facilities, and on the eventual appearance of new products in the marketplace.

As the Governmental structures for regulating the activities of the chemical industry continue to grow, I would hope that there will be a greater sophistication in our approach to regulation. This sophistication should enable both industry and Government to know in advance the ground rules for judging the acceptability of products—ground rules which will not be constantly changing. Of particular importance in this regard is a more consistent approach among Governmental agencies and particularly agencies promulgating regulations directed to the same chemical classes. The relationships between workplace standards, levels of food contaminants, and effluent and emission standards, for example—all directed at the same chemicals—need to be more clearly recognized than ever before.

Trends in the Development of Chemicals

During the next decade, many more chemicals will be in commerce. At the same time the properties of chemicals—both old and new—will be better understood. Consequently, the list of chemicals considered hazardous to man and the environment will undoubtedly be much longer. Also, improved research and analytical capabilities will show that the effects of these chemicals—acting individually and synergistically—are much farther reaching than currently recognized effects.

In many branches of the chemical industry, including your activities, research will continue to illuminate opportunities for use of substitute products. I am sure that increasing agricultural pressures for phosphates, for example, make you keenly aware of the importance of such efforts. In this regard a continuing search for less hazardous substitute products should become a hallmark of your research, recognizing that in the short run such substitutes may be more expensive and less profitable. However, in the longer term the introduction of such substitutes may well be less

expensive to all concerned than the introduction and subsequent withdrawal of cheaper products with questionable health or environmental risks.

From the toxic substance point of view the quality of life in the Chemical Age of the Eighties, depends, in large measure, on the outcome of the competition between economic growth on the one hand and the sophistication in approaches to responsible regulation—by both industry and Government. Clearly, more people will be exposed to more chemicals in more situations. Hopefully, we can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

THE NEED FOR TOXIC SUBSTANCES LEGISLATION

Beginning in 1971, the Administration and Congress have attempted to gain enactment of the Toxic Substances Control Act, and it seems almost certain that these efforts will be revived within this Congress. This legislation has often been described as "front-end" legislation designed to prevent problems rather than simply providing a reaction after chemical contaminants have caused severe environmental or health damage. Also, preventive action early in the life of a chemical could minimize the economic disruptions attendant to corrective actions. Another welcome aspect of this legislation is its explicit call for a more deliberate balancing of risks and benefits prior to Governmental regulatory intervention in commercial activities. Finally, the legislation provides the basis for assessment of the entire life cycle of problem chemicals in determining how best to ameliorate the problems. Too often under existing legislative authority, we focus on the manifestation of the problem which is regulatable under existing authorities rather than on those aspects that are at the root of the problem.

The proposed legislation would give EPA new authority for (a) information acquisition on commercial chemicals, and (b) regulatory actions on chemicals not now subject to regulation under other authorities. EPA could require testing of chemicals which are suspected to pose unreasonable risks and also require other information from manufacturers including the name of the substance, chemical formula, amounts produced, uses, and known by-products. Confidential information would, of course, be respected. When shown to be necessary, and only then, EPA could restrict the use and distribution of chemicals that pose unreasonable risks.

While the final version of the legislation may influence the choice of the initial EPA activities in carrying out the provisions of the law, it seems clear that the following areas should be high on the agenda for early attention:

- Elaboration and articulation of the criteria or sets of criteria to be used in weighing risks versus benefits, and in determining when regulatory action is needed. Clear understanding by both industry and Government of the ground rules for restrictions seems essential.
- Determination of the character and scope of initial testing requirements and identification of specific chemicals or classes of chemicals of particular immediate concern. While the selection of substances to be covered by the standards for test protocols that are initially promulgated will in large measure reflect near-term judgments of experts concerning likely hazards and inadequacy of current data, concurrent work is needed to provide a better basis over the longer term for selecting areas of concern.
- Development of regulations setting forth timing, coverage, content, and format of the reporting requirements for chemical manufacturers and processors, including both annual reporting and premarket notification.
- Establishment of a data system for handling the industrial reports and test results that are submitted. Experience in the pesticide area, for example, underscores the importance of early attention to establishing efficient and decision oriented procedures if large numbers of reports are to be useful in assessing problems in a systematic fashion.

While we are uncertain as to the precise course of Congressional action concerning this legislation, we anticipate that toxic substances bills will be reintroduced in both the House and the Senate within the next few weeks. I suspect that they will be generally along the lines of the *Conference Committee Working Print* which was prepared in December in an effort to bring closer together differing Senate and House positions in several key areas. However, additional modifications will undoubtedly be incorporated by each chamber. Presumably another round of hearings will be held during the spring, and it will not be surprising if the

legislation is again referred to a Conference Committee by summer.

Our understanding is that both environmental and labor groups will be pressing vigorously for early enactment of legislation. These groups have definite views as to some of the provisions of such legislation. With regard to industry you are in a better position than am I to predict the position that will be taken by different segments of industry.

While the Administration has been clearly on record as strongly supporting this type of legislation in the past, the current position on the legislation is still being formulated.

RECENT ENACTMENT OF DRINKING WATER LEGISLATION

Towards the end of the last Congress, the Safe Drinking Water Act was passed providing EPA with authority to conduct a wide swathe of activities ranging from standard setting, to monitoring and research, to assessing availability of water treatment chemicals, to training and technical assistance. Drinking water is one possible resting place for some of the chemicals which are of interest to your industry. Also, each of us consumes about two liters of water each day. Therefore, comments on the toxic substances aspects of this new authority may be of interest. I will touch only on a few aspects of the new law, and specifically on those aspects for which my Office has some responsibility.

You will recall the reports of last fall concerning suspected carcinogens in drinking water supplies in several cities, and particularly organics in the New Orleans water supply. These reports were the principal force in triggering the somewhat unexpected Congressional action. Indeed a specific provision was incorporated into the law calling on EPA to take steps to clarify and reduce the risks associated with carcinogens in drinking water. This requirement has led to a series of actions designed to respond to this public health concern. An extensive program of monitoring a number of water supplies throughout the country is underway. Analyses of the health effects of known contaminants in drinking water are being expanded. Investigations of the feasibility and costs of removing contaminants from water supplies are being accelerated. Obviously, these types of activities have been carried out in the past. However, the current efforts are broader and more ambitious than ever before.

New efforts are underway to clarify the source of the drinking water contaminants. In many cases, the sources are industrial discharge; sometimes the contaminants may be traceable to pesticides or fertilizer runoff; and in other cases natural background levels may be responsible. Correlating specific sources of chemical discharges into the environment with contaminants found in specific water supplies is not easy, however. This task is further complicated when the quantities of the chemicals are very small.

Perhaps the key element of the new legislation is the determination of the levels of contamination in drinking water which are acceptable for specific chemical pollutants. This determination is to be made on the basis of both public health considerations and technical and economic feasibility. Within the next two months EPA is scheduled to propose interim standards for about 30 contaminants with revised standards scheduled for promulgation in about two years. It seems likely that the revisions will include more chemicals, including at least some of the organics which are of particular immediate concern.

In very simplistic terms, there would seem to be two alternatives in reducing contaminant levels which exceed prescribed standards: applying control technologies at the water supply (e.g. filtration, coagulation) or reducing the source of the contaminant (e.g. at the effluent pipe, during field applications). In either case there will be costs involved, and hard decisions must be made as to the most appropriate distributions of these costs.

TESTING AS A KEY TO BETTER UNDERSTANDING

In all of these areas—in all of our regulatory decisions—we are faced with uncertainties. The health data are usually soft; the data on persistence sparse; and the data on ecological effects almost nil. Yet actions must be taken. We cannot afford to allow our environment to become a testing laboratory, nor our general population the test species. At the same time no one advocates that the absence of data indicates that a chemical is environmentally acceptable.

Thus, in my view, a key to responsible decision-making is better information on chemicals under test conditions simulating, to the extent possible, the types of exposure encountered in the general environment. And it is industry that has the responsibility to insure that such testing is conducted on the products it sells. And it is the responsibility of Government to insure that industry is fully aware of the type and extent of testing that will be considered adequate in the regulatory process.

Indeed, improved information—and particularly test information—as an essential ingredient for responsible decision-making is the heart of the Toxic Substances Control Act. With such legislation on the books many of the currently disruptive uncertainties over Governmental and industrial responsibilities will be clarified. There will be a real opportunity for productive efforts to jointly insure the enhancement of our environment while promoting the continued viability of the chemical industry.

Whether we be concerned with detergent builders or optical brighteners, with borax or higher benzenepolycarboxylates, we must consider both the commercial benefits from our activities and the necessity for environmental safeguards. We all know that the balancing of costs, risks, and benefits is not unique to the chemical industry; indeed it is the essence of many of our daily activities as we drive our car to the corner drugstore for a carton of cigarettes. However, when the beneficiary of an activity is different from the person exposed to the risk, we can no longer be casual in balancing costs, risks, and benefits. Thus, a more deliberate approach to societal decisions is the challenge of the years ahead.

TOXIC CHEMICALS AND REGULATORY DECISION MAKING PHILOSOPHY AND PRACTICALITY

Conference on Principles of
Decision Making for Regulating
Chemicals in the Environment
National Academy of Sciences
New Orleans, Louisiana
February 18, 1975

THE GENERAL FRAMEWORK

Integration of economic, energy, and environmental concerns. The need to avoid the extremes and to exhibit moderation in applying environmental controls. Balancing costs, risks, and benefits. Maintaining environmental objectives while adjusting the short-term timetables to accommodate economic problems. The inevitability of some level of risk in everything we do.

This rhetoric, characterizing the current climate surrounding the environmental movement, appears appealing and easy to grasp. But what does it really mean as we address specific regulatory actions directed to toxic chemicals?

On a macro scale, we sometimes feel we are able to express the dollar costs of environmental control measures, with some confidence in our estimates. Recently, drawing on the practices of the statisticians, we have begun to manipulate health effects data in order to quantify the level of risk and the size of the population at risk. At the micro level, it often seems still easier to estimate the impact of regulatory actions, answering such questions as: What will a specific pollution control device cost in a specific plant? What will the resultant contaminant levels be in the stream or in the drinking water? Is this level below a "no effects" level?

However, in my view the aggregation of micro impacts is far more complicated than summing up the parts. For example, a risk factor of 1/1,000,000 appears different when viewed from the perspective of the 1 than from the perspective of the other 999,999. Also the cumulative effect of regulatory actions, together with the uncertainty of future actions, has a dramatic effect on the whole climate of doing business. Many aspects of this effect are difficult to identify, let alone quantify. Second guessing the current and future attitudes of regulatory agencies is becoming a way of life within many chemical companies as they reach decisions on the amount of resources to devote to R&D, the level of investments in introducing new products or continuing old products in the face of evidence suggesting possible environmental problems, and the pollution abatement conservatism to be built into the design of new plants.

TRENDS IN REGULATORY DECISION MAKING

The legislative history of toxic substances regulation is punctuated with inconsistencies as to the weight to be given costs, risks, and benefits in decision making. The most recent addition to the annals of environmental law, the Safe Drinking Water Act, addresses directly the perennial question of the weight to be given to public health considerations in determining enforceable contaminant levels. This law calls for both (a) health based contaminant levels—or health goals—and (b) enforceable contaminant levels which explicitly take into account technological feasibility and reasonableness. Similarly, the many versions of the proposed Toxic Substances Control Act have consistently highlighted the need to weigh all relevant factors including economic and technological considerations in reaching regulatory decisions. As you know, this philosophy is not expressed with similar clarity in certain sections of the Clean Air Act and the Federal Water Pollution Control Act.

Meanwhile, we are increasingly requiring more broadly based assessments of the impact of regulatory decisions—environmental assessments, economic assessments, and recently inflationary assessments. Usually the procedure is to postulate a numerical standard for a toxic chemical or a specific type of limitation on the use of the chemical, with the restriction designed to reduce environmental levels to the point that concerns over health or environmental damage disappear. Then an assessment is carried out to see if the favorable environmental impact from the restriction warrants the concommitant economic costs. If the costs are too high, the level of control is adjusted until an appropriate balance is reached. Unfortunately, to date this balancing act has been ad hoc at best, while at the same time our new authorities are calling for more systematic approaches to such balancing. As the judiciary becomes more deeply involved in toxic substances, it seems essential that these approaches must improve both in form and in substance if regulations are to be sustained by the courts.

In our zeal to balance risks and benefits in some quantitative way, we frequently try to place numbers on the risks associated with very uncertain health

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data. More often than not, in the quantification process we drop the margins of error from our deliberations. This has been particularly true in the carcinogen area. Largely as a result of the work of statisticians beginning ten or more years ago, there are now techniques for estimating risk factors. However, too often the lawyers and economists seize upon these numerical risk factors, frequently forgetting that these experimentally derived estimates may in fact have a very shaky relevance to the real world.

NEEDS OF REGULATORY DECISION MAKING IN THE NEAR FUTURE

Clearly, our goal is to improve the decision-making process, a process that is usually plagued with insufficient time and with unbelievably soft data. Nevertheless, decisions must be made, decisions that hopefully will be both sensible and defensible. We need to better use existing data—to better assemble what we have, to see more clearly what we don't have, to make reasonable extrapolations across the data gaps, and then to make judgments which best reflect the interests of society. If legal constraints inhibit judgments which best serve society, we should seek changes in the law.

We need to better orient our data collection and manipulation activities so that the information is arrayed in a way in which it is more relevant to decision making. I need not describe for you the difficulties in trying to derive the roots for numerical standards on the basis of a toxicological experiment which was designed to expand the state-of-the-art of toxicology. And, finally we need to be able to better integrate data concerning a variety of considerations—health, persistence, control technology, economic dislocations. Is it possible to move away from the past efforts of comparing apples with oranges—away from the fruit salad approach towards a truly blended regulatory punch?

THE SCOPE OF THIS MEETING

This meeting is directed principally to advancing the state-of-the-art in reaching regulatory decisions on toxic chemicals which for one reason or another have already been identified as highly suspect in causing serious environmental or health problems. The suspicion may have arisen from recent epidemiological findings, toxicological experiments, or monitoring data, or it may reflect an accumulation of scientific or public concerns not necessarily tied to recent revelations. It may have resulted from deliberate efforts to search out problem chemicals. In any event, given a problem chemical, how can we more effectively decide whether regulatory action is in order, and if it is, how tight or how loose the regulation should be? We are particularly concerned with decision making which must be carried out in the near term in the absence of what purists—or perhaps even reasonable men—would call adequate time or data. There is really no option to delay the decision until better data are available. This does not mean that the interim decision is necessarily the final decision; and indeed, I have not been involved in a single regulatory decision of any significance that has not included as part of the package the requirement to collect better data so that the decision can be reviewed and perhaps improved at a later date.

There are several concerns closely related to the regulatory decision which are not a principal focus of this meeting although it is recognized that you cannot totally neglect these aspects. One area of considerable importance which is being explored in a variety of other forums concerns methods for selecting from the world of chemicals those chemicals or chemical activities which require priority regulatory attention. A second area receiving considerable attention within EPA is the selection of the most appropriate legal authority for reducing identified problems. For example, what are the respective roles of Effluent Guidelines and Toxic Effluent Standards under FWPCA; when are New Source Performance Standards more appropriate than Hazardous Pollutant Standards under the Clean Air Act; and which sections of the Pesticide laws can most appropriately be invoked to curtail certain problems? A third important aspect relates to the generation of test data, a topic which has already been explored in some detail by the Academy.

At this session we would like to emphasize the problems of decision making with less than optimal data. A secondary interest, of course, relates to the shaping of data collection activities, particularly in those instances when there is sufficient time to improve the data base before a regulatory decision is necessary.

In general, we are concerned with two types of regulations: firstly, product limitations where the manufacturing, use, distribution, or disposal of a chemical is regulated such as in the case of pesticides or chemicals under the Toxic Substances Control Act; and secondly, the determination of the acceptable levels for pollutants—expressed as numerical standards or as a control technology requirement—such as in the case of hazardous air emissions, toxic water effluents, drinking water

contaminant levels, pesticides tolerances, and the like. Further complicating the task is our special interest in multimedia contaminants.

EXAMPLES OF PRACTICAL REGULATORY PROBLEMS

Let me cite three regulatory areas which exemplify the types of concerns that this Conference might address. During the next several years, EPA will be involved in a variety of decisions in all of these areas. There are, of course, other areas as well, and particularly pesticides and air emissions problems, which my colleagues can address.

Regulatory Actions under the Toxic Substances Control Act

The proposed Toxic Substances Control Act would give EPA the authority to prevent or limit production, distribution, or use of selected chemicals or require that they be labeled with instructions concerning use or disposal. The most recent versions of the law require that in reaching regulatory decisions the Administrator consider:

- The effects of the substance on health and the magnitude of human exposure,
- The effects of the substances on the environment and the magnitude of environmental exposure, and
- The benefits of the substance for various uses and availability of less hazardous substances.

After considering these factors he could impose regulatory action if he determines that there is an "unreasonable risk" to health or the environment.

The purpose of this session is not to try to determine what is an unreasonable risk since that judgment must be made on a case-by-case basis. However, we are hopeful that you can assist in further clarifying the factors that should be weighed in reaching such a judgment and in setting the ground rules for arraying data in a way that the judgment will be as fully informed as possible. Again, it is important to keep in mind that the data which will be arrayed will inevitably be far from complete.

As one point of departure in our internal efforts to assemble data in an orderly fashion for determining the need for regulations under this proposed law, we have identified the following five steps:

- Assessment of the effect of various levels of exposure of a chemical or its derivatives on man or the environment;
- Assessment of the likely levels of exposure through material balance analyses;
- Confirmation by monitoring of actual exposure levels;
- Determination of the likely reduction in exposure levels and attendant effects through alternative regulatory actions; and
- Assessment of the economic and social costs of the alternative actions.

Under each of these categories we are attempting to develop checklists of items to be considered. I am sure that these data categories can be improved, but perhaps of equal importance is how the data from these categories are to be meshed.

National Primary Drinking Water Regulations

In about two years EPA will propose revised National Primary Drinking Water Regulations for contaminants in drinking water, including probably several dozen chemicals. These regulations must take into account both public health considerations and feasibility of attainment. Thus, it seems necessary to consider (a) health effects at various contaminant levels, (b) monitoring data showing the current and projected range of contamination in water supplies, (c) costs involved in reducing high levels to lower levels at the water supply, (d) feasibility and costs of monitoring low levels, (e) sources of the contaminants, and (f) costs of reducing these sources as an alternative approach to cleaning up the water after it is contaminated. The problem of data collection and analysis is particularly complicated since a single standard will apply to 40,000 water supplies of all sizes and character. Short term variances will help with some of the extreme cases. However, the need for reliable statistical sampling will nevertheless be a complicating factor. The problem as I see it is at least twofold: collecting and displaying the data in these categories in a meaningful way, and integrating the data in a way which will enhance the soundness in reaching judgments as to required levels. Again I would add that much of the data may be soft and not susceptible to easy quantification.

Toxic Effluents that Cause Health Problems

We are currently involved in a major effort to determine which chemicals currently being discharged into our waterways constitute a health hazard. One starting point is an examination of monitoring information from drinking water supplies, fish products, and recreational areas concerning the presence of chemicals, and isolating those chemicals that are (a) suspected to have adverse health effects at relatively low levels, (b) discharged by industrial facilities, and (c) sufficiently persistent to reach man via the recreational, drinking water, or food routes.

It is not too difficult to identify a few such chemicals; however, it is far more difficult to determine whether effluent controls on these chemicals are warranted and if so, the degree of control that is appropriate. The chemicals will probably usually be present in trace amounts, and the health hazards from these trace amounts, even for carcinogens, are far from clear. The incremental decrease in the trace amounts, and the attendant health implications, which will be achieved by turning off or reducing selected sources is similarly not clear, particularly if industrial dischargers are not the only source of contaminants. Finally, whether the control costs are warranted by the incremental health gain is also far from straight forward. We anticipate that we will be grappling with this problem for several years, and advice and suggestions on appropriate methodologies would be very welcome.

THE OUTPUT FROM THIS CONFERENCE

What can be realistically accomplished during the next several days and during the report writing that will continue for several months?

Perhaps most importantly, a greater sensitivity to the multiplicity of societal interests bearing on regulatory decision making will emerge—certainly among the participants and hopefully among the recipients of the report. This sensitivity should in turn lead to a higher level of sophistication in our decision making.

General principles which can serve as guideposts in the field of chemical regulation would be welcomed by all participants in the regulatory process—the regulator, the regulatee, and the adjudicator. Such principles are particularly timely as the influx of new people into this field continues to grow. The scope, general appreciability, and specificity of these guideposts are of course the crux of the deliberations during the next several days.

With the benefit of hindsight, we should be able to identify common shortcomings in past decisions which an improved methodology can overcome. And surely as we consider the types of decisions ahead, specific ideas and suggestions will undoubtedly emerge.

Finally, we are searching for practical suggestions as to how we can significantly improve our data base for decision making without "breaking the bank."

THE CONTROL OF TOXIC SUBSTANCES IN THE YEARS AHEAD

From the toxic substance point of view the quality of life in the chemical age of the Eighties depends, in large measure, on the outcome of the competition between economic growth on the one hand and the sophistication in approaches to responsible regulation—by both industry and Government. Clearly, more people will be exposed to more chemicals in more situations. Hopefully, we can develop the necessary precautionary measures that will limit exposure to chemicals when necessary, but not unnecessarily curtail commercial activities.

There is, of course, a danger that society will not act responsibly toward toxic substances through its Government and other institutions, with the inevitable outcome of endless legal confrontations. The entire approach to toxic substances could become bogged down in the courts. To avoid such a situation, the highest quality of Governmental leadership in this area seems essential—leadership characterized by technical credibility and openness in dealing with controversial data. You have a genuine opportunity to help stimulate such leadership.

We all know that the balancing of costs, risks, and benefits is not unique to the control of chemicals; indeed, it is the essence of many of our daily activities as we drive our car to the corner drugstore for a carton of cigarettes. However, when the beneficiary of an activity is different from the person exposed to the risk, we can no longer be casual in balancing costs, risks, and benefits. Thus, a more deliberate approach to societal decisions is the challenge of the years ahead.

CURRENT TRENDS IN THE CONTROL OF CHEMICALS

Conference on Environmental Aspects
of Chemical Use in
Rubber Processing Operations
Akron, Ohio
March 12, 1975

THE RAPID GROWTH OF CHEMICAL PROBLEMS

During the last several years the number and frequency of harmful incidents involving toxic chemicals have increased dramatically. Hardly a week goes by without a new chemical emerging as an immediate health or environmental problem, and the public outcry over carcinogenesis and other chronic effects of exposure to chemicals seems to have literally exploded.

All levels of Government are taking steps in response to the demands for action to clarify and reduce the risks attendant to chemical exposure. No longer are pollution problems viewed simply in terms of asthetics, inconveniences, or ecological degradation; but they are now tied more closely than ever before to very personal human health concerns. No longer are the long drawn-out timetables acceptable for corrective steps with regard to toxic chemicals. No longer will the public accept the philosophy that chemicals must be assumed safe until proven hazardous. No longer are latent problems, such as the mutagenic effects of chemicals that may appear only in future generations, to be ignored. No longer are chemicals the unique concern of only the manufacturers, the distributors, and their employees, for the Chemical Age of the Seventies has engulfed our entire society.

I need not review for this audience the unsettling chain of events triggered by the linkages established last year between cancer of the liver and exposure to vinyl chloride. Many of the companies represented here have been deeply involved from the outset of this very tragic development, a development rooted in the environmental complacency of the industry during the forties, the fifties, and the sixties. We have all become painfully aware of the difficulties in assessing the risks associated with very low levels of exposure to this chemical and in taking corrective actions to reduce these risks. I am sure that all agree that we can and must do better in the future in preventing these types of tragedies—and particularly in identifying and assessing problems before the fact rather than after the damage is done.

Already tens of thousands of chemicals are in commerce, and the number is increasing every year. Little attention has been given to the environmental properties of many of these chemicals. Constantly evolving research and analytical techniques are revealing that the potential effects of many others are much farther reaching than previously suspected. In short, during the years ahead all of us will be exposed to many more chemicals in many more situations, and the list of chemicals known or believed to pose a threat to man or the environment will be greatly expanded.

Our market forces are not designed to insure environmental equity, and the risks and benefits associated with chemicals are not evenly distributed throughout our society. The archaic concept of voluntary exposure to chemicals—that we have a choice as to whether we want to come into contact with chemicals—has been replaced with the hard reality that in fact the individual citizen has little control over the chemicals to which he is exposed. Thus, Governmental involvement in the chemical arena will undoubtedly increase to keep pace with the growing chemical burden in the environment.

THE DEVELOPMENT OF THE LEGISLATIVE BASIS FOR CONTROLLING TOXIC CHEMICALS

For many years the Federal Government has been deeply involved in chemical regulation through the activities of the Food & Drug Administration, and more recently in controlling pesticide use. The Clean Air Act and the Federal Water Pollution Control Act have special provisions directed to toxic and hazardous chemicals in addition to their broader provisions which also encompass chemical pollutants. Indeed, these activities have to a large extent established the framework for the current spread of programs throughout the industry directed to product safety and environmental control.

During the past several years the Department of Transportation, the Occupational Safety and Health Administration (OSHA) of the Department of Labor, and the Consumer Product Safety Commission have significantly expanded their efforts directed to toxic chemicals. Of particular interest to EPA and OSHA is the close interrelationship between concerns over chemicals in the workplace and the possible discharges of these same chemicals directly or indirectly into neighborhoods near industrial facilities as the result of air emissions or liquid effluents. In many cases a large share of these nearby residents are the workers

who may be exposed to the same chemicals on and off the work premises. Also, we are concerned that in dealing with persistent chemicals the long standing approach of better ventilation does not appear to be an acceptable solution to meeting workplace standards.

In December the Safe Drinking Water Act was somewhat unexpectably enacted. The rapid Congressional action on this legislation was prompted by reports of trace amounts of organic chemicals—including several possible carcinogens—found in several drinking water supplies, and particularly New Orleans. This legislation, which calls for establishment and enforcement of maximum contaminant levels in nation-wide drinking water supplies, has far reaching implications for industry. It seems unlikely that municipalities will invest large sums of money in removing chemical contaminants from their water supplies without first attempting to identify and control the sources of these contaminants. In many cases the sources of concern will undoubtedly be industrial dischargers.

The proposed Toxic Substances Control Act offers an unusual opportunity to improve the soundness and the fairness of regulatory decisions concerning toxic chemicals. The heart of this proposed legislation is the acquisition of more authoritative information concerning both the risks and the benefits associated with chemical activities. Special emphasis is placed on better test information which is predictive of the behavior of chemicals in the environment. A second aspect of this proposed legislation is provision for controlling serious toxic chemical problems which cannot be adequately addressed under other existing authorities.

An improved information base is critical to better decisions concerning Governmental intervention in chemical activities under a variety of regulatory authorities. At the present time decisions are being made on the basis of very sparse data. Even in the absence of such information, decisions will continue to be made, for action in this field cannot be delayed. In this regard, the lack of hard data concerning chemical behavior should not be considered a license for continued production and use of the chemicals any more than we can assume that activities should cease until they are proven to be absolutely safe.

INTERCEPTING THE PROBLEMS AT THE OUTSET

A main feature of the Toxic Substances Control Act is the emphasis on identifying problems early in the commercial lifetime of chemicals—before there has been irreversible environmental damage and before major economic investments are in place. At present we find ourselves constantly reacting to problem chemicals which are already widely dispersed throughout our economy—chemicals which have already caused environmental problems and which represent substantial investments for suppliers, manufacturers, and distributors. Corrective measures invariably mean substantial economic dislocations.

With 500 to 700 new chemicals being introduced into commerce every year, it is only sensible to make the extra effort to insure that these new products are not going to cause problems later in their lifetime. The extent of the research and testing needed to reach a judgment as to potential environmental problems will vary among chemicals and among uses of the chemicals. However, the ground rules for early assessment of chemicals need sharper clarification and greater acceptance by all concerned. In my view, the recent report of the National Academy of Sciences *Principles for Evaluating Chemicals in the Environment* has been a major step forward in this regard. Further development of the concepts set forth in this report, and particularly relating these concepts to practical problems, needs priority attention.

Of course, any Governmental intervention during the pre-market phase must be sensitive to the financial realities of R&D activities. Particularly important is the need to avoid additional delays due to uncertainty as to Governmental actions. Also, the cumulative effect of actions directed to individual chemicals can dampen the overall climate for research. Finally, protection of the confidentiality of activities directed to new chemicals is of critical importance.

Unfortunately, this approach of early identification and prevention of environmental problems and economic dislocations will not help in addressing chemicals currently in large scale production. It is indeed unfortunate that this "pay now and save later" philosophy was not adopted many years ago. As problems continue to arise with high volume chemicals, the short-term economic adjustments will undoubtedly be severe.

COST/RISK/BENEFIT CONSIDERATIONS

Recently the Government has significantly increased its efforts to not only assess but also to try to balance the costs, the risks, and the benefits involved in regulating toxic chemicals in the environment. To the extent possible regulatory

activities should be judged on the basis of their total impact on society—impact on the standard of living, effective resource utilization, and preservation of social as well as environmental values.

This change in direction in approaching regulatory decisions has in large measure resulted from a reorientation in the nature of some of the legislative authorities under which EPA operates. For example, the new Safe Drinking Water Act and the proposed Toxic Substances Control Act are very explicit in their requirements to take into account economic as well as health and environmental considerations. On the other hand certain provisions of the Clean Air Act and the Federal Water Pollution Control Act are far from clear as to the weight, if any, to be given to economic considerations. In a related development, recent court action concerning the feasibility of the workplace standard for asbestos has had a considerable impact on the approach of OSHA.

Despite growing sophistication in the approach to controlling toxic substances, rigorous cost/risk/benefit analyses will seldom be possible; for adequate time, data, or resources will usually not be available to satisfy a purist. However, we can certainly do better than we have in the past.

Many of us have had direct experience in attempting to draw conclusions from biological data which are invariably "soft." At the same time pragmatic economists tell us that their data on benefits may be even softer—and probably characterized by uncertainty, incompleteness, and perishability. They are particularly reluctant to provide estimates of the societal benefits to be derived from the use of chemicals which contribute to improved health and living conditions, to greater personal conveniences, to new recreational and asthetic opportunities, and to maintenance of national defense. Often, they are even less willing to speculate as to how the marketplace will react if a specific chemical is removed or if its price is increased as the result of environmental controls. In short, the economists can provide a shopping list of some of the factors to be considered in regulatory decision making, but they provide relatively little guidance as to how these economic factors are to be weighted or integrated or how they are to be meshed with other considerations.

Several points related to costs seem to be clear, however. If there are increased costs attendant to environmental control, these costs will be eventually passed on to the consumer. Secondly, there will probably be local impacts attendant to specific types of regulatory activities, and particularly limitations on the manufacture or use of chemicals. These local impacts can include business set-backs, employment dislocations, and even depressed real estate values. And finally, in general the market is sufficiently flexible and our innovative capacity sufficiently high to fill promptly the vacuum caused by the loss of a single product with alternative products or approaches to providing a similar service.

In view of the critical importance of cost/risk/benefit assessments to responsible decision making, we have recently launched several major efforts to refine the methodologies which can illuminate in advance the implications of regulatory decisions. It is particularly important that value judgments not be disguised in manipulating the data base and that the bases for decisions be structured in such a way that the public can understand the rationale that is used.

THE SPECIAL RESPONSIBILITIES OF INDUSTRY

In recent years, many segments of industry have made very significant investments to control the discharge of effluents and emissions into the environment. These steps have been taken in large measure in response to Governmental requirements at the Federal, State, and local levels. There seems to be little doubt that such actions have had a dramatic effect in slowing the rate of degradation of our environment. However, all will agree that we still have a long way to go in cleaning up our air and water and in preserving our landscape.

Similarly, industry has over the years expanded its efforts to insure the safety of its chemical products—safety as viewed from the perspective of the worker, of the housewife, and of the general population. Such efforts have been spurred to a great extent by Governmental regulations, in some cases by the latent threat of lawsuits, and at times simply by good business practices. For many years, direct acute effects of chemicals have, of course, been of major concern; and more recently, complementary efforts have been directed to the longer term and more subtle health and ecological effects.

In some cases, industry has gone far beyond the requirements laid down by Government for pollution control levels to be achieved and for safety requirements. For example, one major chemical company has adopted the near term goal that all new plants be designed to achieve zero discharge with regard to process liquid waste effluents. Some companies have significantly expanded their staffs of toxicologists to address health problems beyond those of immediate interest in Governmental regulations. Other companies are conducting

ecological effects tests on chemicals which by regulation are only required to be tested for their health effects. However, our general impression is that most companies are not moving much faster on the environmental front than the rate at which they are required by legally enforceable regulations.

Industry has a special responsibility to know what chemicals are released during its manufacturing activities and during the use of its products. Further, industry has a responsibility to know the levels of human and environmental exposure to chemicals resulting from such releases. Industry has a responsibility to know the likely hazards, if any, associated with such exposures and to insure that the public is aware of these hazards. Finally, industry has the responsibility to take all possible steps to minimize these hazards.

These are societal responsibilities which transcend legal obligations imposed by Federal, State, or local regulations. In the years ahead these responsibilities must be given equal weight with product performance in judging a company's contribution to society.

To accept these types of responsibilities implies new dimensions in corporate activities, particularly with regard to physical monitoring and to studies of health and environmental effects of chemicals. However, I am optimistic that the industrial leadership of this country will respond to the challenge—that this leadership will show restraint in foregoing attractive commercial activities when necessary in the face of environmental uncertainties, that it will expand its search for less hazardous products, and that it will reward its management for contributions to the health of the nation and to the conservation of ecological resources with as much enthusiasm as it rewards employees for increasing sales.

A NEW DEPARTURE TOWARDS COMMON UNDERSTANDING

This Conference signals a new departure in our efforts to better understand the character, scope, and implications of problems associated with chemical activities. As additional activities in this field are contemplated by Government, industry, labor, and other interested groups, it seems imperative that we have an authoritative examination of where we are today—the effect and implications of environmental actions already instituted by Government and industry and their future plans and programs. Hopefully with a common base of understanding, deliberations within Government, industry, and labor will be more rationale, better, balanced, and more objective. In the absence of this common point of departure, there will only be a spiralling of confusion, suspicion, and acrimony on the part of all concerned.

This session, which draws on the expertise and insights of representatives of many of the concerned organizations, is designed to help establish the baseline as to the current situation. Hopefully, the formal program represents but a small portion of the exchanges that will take place during the next two and one-half days. We are very encouraged by the large industrial participation in this meeting. Of particular interest to us are the steps being taken by industry. For example, we know that massive R&D efforts are underway to correct the problems associated with PVC activities. To what extent are similar efforts being extended to the rubber processing activities of these same firms who have been so involved with PVC during the past year?

The industry's concern over chloroprene, styrene, and acrylonitrile, for example, have been well publicized. Similarly, Government's concerns over gross pollution effects (e.g. BOD, COD, TSS, criteria air pollutants) are being reflected in water effluent permits and in air emission controls. While we should understand these actions, which are important not only in themselves but also as either successful or unsuccessful case histories, probably of even more importance at this Conference is to look ahead into future areas of possible concern—for we all share an overriding interest in substituting preventive for corrective actions.

I am pleased to note that the formal program calls for an examination of progress in pollution control, a review of the characteristics of specific chemicals, a discussion of innovative uses of waste products, and an assessment of the role of epidemiological studies. All of these topics are central to current efforts in controlling toxic chemicals. It seems clear that in the future:

- pollution control requirements will give much greater emphasis to limiting discharges of selected chemicals;
- the environmental behavior of many more chemicals will be examined in detail;
- productive uses of waste products will become more and more of a reality; and
- epidemiological studies to correlate exposure to chemicals with human health effects will expand considerably.

We give high importance to this Conferen[illegible] - which is the first of several such meetings directed to various aspects of chemical usage. This effort is enthusiastically supported by the Administrator of EPA and by the Chairman of the Council on Environmental Quality. We are hopeful that it will make a major contribution to wiser decisions by Government and by industry—decisions that can have a significant impact on the price we pay for the fruits of this Chemical Age.